Block, amend, delay: tobacco industry efforts to influence the European Union’s Tobacco Products Directive (2001/37/EC)

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Note to readers

Much of the evidence in this report is based on internal tobacco industry documents released as a result of litigation in the United States. Those wishing to view the documents cited can follow the weblink for each document given in the reference section. Those wishing to search for additional documents can conduct their own on-line searches following instructions given in Appendix 5.
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<th>Abbreviation</th>
<th>Description</th>
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<td>BAT</td>
<td>British American Tobacco</td>
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<tr>
<td>CBI</td>
<td>Confederation of British Industry</td>
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<tr>
<td>CECCM</td>
<td>Confederation of European Cigarette Manufacturers</td>
</tr>
<tr>
<td>CEDT</td>
<td>Confederation Europeenne des Detaillants en Tabac</td>
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<tr>
<td>CoM</td>
<td>European Council of Ministers</td>
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<tr>
<td>CoR</td>
<td>Committee of the Regions</td>
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<tr>
<td>COREPER</td>
<td>Committee of Permanent Representatives</td>
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<tr>
<td>DG SANCO</td>
<td>Directorate General of Health and Consumer Protection (also known as DG V)</td>
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<tr>
<td>DG</td>
<td>Directorate General</td>
</tr>
<tr>
<td>DTI</td>
<td>Department of Trade and Industry (UK) (now Business, Enterprise, and Regulatory Reform - BERR)</td>
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<tr>
<td>EACP</td>
<td>Europe Against Cancer Programme</td>
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<tr>
<td>ECJ</td>
<td>European Court of Justice</td>
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<td>ECMA</td>
<td>European Carton Makers Association</td>
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<tr>
<td>EESC</td>
<td>European Economic and Social Committee</td>
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<td>EP</td>
<td>European Parliament</td>
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<td>ESTA</td>
<td>European Smoking Tobacco Association</td>
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<td>EU</td>
<td>European Union</td>
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<td>FETRATAB</td>
<td>Federation Europeenne des Transformateurs de Tabac</td>
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<td>FCTC</td>
<td>Framework Convention on Tobacco Control</td>
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<td>GATT</td>
<td>General Agreement on Trade and Tariffs</td>
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<tr>
<td>GITES</td>
<td>Groupement des Industries Europeennes du Tabac</td>
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<tr>
<td>ISO</td>
<td>International Organization for Standardization</td>
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<td>JTI</td>
<td>Japan Tobacco International</td>
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<tr>
<td>MEP</td>
<td>Member of European Parliament</td>
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<tr>
<td>MP</td>
<td>Member of Parliament (UK)</td>
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<tr>
<td>MS</td>
<td>Member States of the European Union</td>
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<tr>
<td>MSF</td>
<td>Manufacturing, Science and Finance Union</td>
</tr>
<tr>
<td>NGO</td>
<td>Non-governmental organisation</td>
</tr>
<tr>
<td>NMA</td>
<td>National Manufacturers Association</td>
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<td>PM</td>
<td>Philip Morris</td>
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<td>RJR</td>
<td>RJ Reynolds</td>
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<td>SEITA</td>
<td>Société Nationale d'Exploitation Industrielle des Tabacs et Allumettes</td>
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<td>SPS</td>
<td>Sanitary and Phytosanitary Measures (Agreement)</td>
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<td>TBT</td>
<td>Technical Barriers to Trade (Agreement)</td>
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<td>TMA</td>
<td>Tobacco Manufacturers' Association</td>
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<td>TPD</td>
<td>Tobacco Products Directive</td>
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<tr>
<td>TRIPS</td>
<td>Trade-related aspects of intellectual property rights (Agreement)</td>
</tr>
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<td>TTC</td>
<td>Transnational tobacco company</td>
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<td>TWA</td>
<td>Tobacco Workers Alliance</td>
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<td>UK</td>
<td>United Kingdom</td>
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<td>USA</td>
<td>United States of America</td>
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<td>VdC</td>
<td>Verband der Cigarettenindustrie</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>WTO</td>
<td>World Trade Organization</td>
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Executive Summary

Introduction

In 1996, discussion began in Brussels on the need for further tobacco control measures. Following extensive consultation, in November 1999 the European Commission proposed a new Tobacco Products Directive (TPD). The proposal would strengthen existing European legislation on cigarette yields and product labelling by lowering limits for tar, nicotine and carbon monoxide yields and by enlarging warning labels. It also sought to introduce stringent ingredients disclosure provisions and a ban on misleading descriptors such as “light” and “mild”, and aimed to prohibit the export of non-compliant products outside the European Union (EU). The tobacco industry mounted an intense lobbying campaign in response and made at least five legal challenges against the directive. Despite such efforts the directive was enacted successfully in 2001. This study seeks to identify and analyse tobacco sector responses to the directive and discuss the implications for future legislation within the EU and beyond. Such an analysis is particularly timely given the current review of the directive and emerging debates around plain packaging.

Methods

Qualitative analysis of previously secret corporate documents, released into the public domain following litigations in the United States of America (USA), triangulated with other sources, notably interviews with key informants.

Results

The documents reveal that the industry was seriously alarmed when the idea of further control measures was first floated in Brussels in 1996-7. By the time these were formalised into a proposal for a directive in 1999, the tobacco industry had activated a comprehensive response framework. Although initially united in their response, divisions between transnational tobacco companies (TTCs) soon became apparent. Philip Morris (PM), less threatened by the proposed measures given its dominant market share and minimum manufacturing for export, preferred ‘constructive engagement’ to the more aggressive stance taken by its competitors. British American Tobacco (BAT), for example, favoured combative tactics to ‘block, amend or delay’ the directive. This rift jeopardised the cohesive pan-industry approach which had been called for at the outset.

Notwithstanding such tensions, the tobacco companies, acting alone or in various combinations and recognising the need to influence public opinion, developed legal, economic and scientific argumentation designed to shape debates around the directive. The three principal arguments...
advanced were that the directive was “ultra vires”, contravened existing trade agreements, and would have adverse economic impacts.

Despite receiving diverse legal opinions, some of which confirmed the directive’s legality, publicly the tobacco industry forcefully argued that the directive was invalid, claiming that its main legal basis (Article 95) and a later additional basis (Article 133), were inapplicable. It also alleged that the directive was incompatible with obligations under World Trade Organization (WTO) agreements on technical barriers to trade (TBT) and intellectual property rights, invoking strategically useful threats of trade challenges despite the clearly tenuous basis of claimed conflicts. Alleged economic consequences, particularly a threat to jobs, were highlighted with BAT publishing its own economic impact study which focused only on negative economic impacts, overlooking potential health benefits and exaggerating job losses (see section 4.3.3). In addition, science-oriented arguments exploited both the limited technical capacity in the Commission and ongoing debates within the health community around product regulation and were used, particularly by PM, to secure access to Commission officials.

Lobbying efforts were well-organised and informed by a detailed analysis of the EU co-decision procedure, in which legislation must be agreed by the Council of Ministers (CoM, representing Member States) and the European Parliament (EP). Thus the industry carefully targeted the key arguments it had developed to appropriate audiences; their delivery executed in synchrony with the timetable for the directive’s passage through the legislative process.

Lobbying encompassed both direct and indirect approaches. The direct efforts targeted those who could directly influence the text of the directive - Commission civil servants, Members of the European Parliament (MEPs) and national politicians including ministers. Attempts to table industry-authored or industry-favoured amendments were made through the CoM and, in the Parliament, via MEPs, especially those on influential committees. The German government and MEPs were particularly significant in this context. Tobacco companies, led by PM, also entered into a consultative process with the Commission on scientific issues, enabling PM to push its own model of ingredient disclosure.

Indirect lobbying focused on obtaining support from tobacco farmers, suppliers and distributors and the active engagement of trade unions, mobilised by alleged exaggerated impacts on employment. Such protests helped secure generally sympathetic media coverage, assisted by BAT’s placement of letters, articles and advertisements in the press. The TTCs also viewed the directive as a significant enough threat to take legal action after it passed into Community law.
Despite intensive and sustained lobbying, the industry neither prevented the directive from coming into force nor managed to dilute its provisions, being thwarted in its attempts to gain sufficient blocking votes in the EU Council and Parliament. Strong leadership from Commissioner Byrne and his Cabinet, political commitment across traditionally supportive and some traditionally resistant Member States, and the skilful management of parliamentary debates by the Environment Committee’s Rapporteur, Jules Maaten, enabled effective resistance against industry efforts.

**Discussion and Conclusion**

The corporate documents analysed here provide compelling evidence of a methodical and multi-layered strategy to undermine the TPD. Although the directive was passed, the activities of the industry illuminate several key issues for tobacco control and public health in the EU.

First, the legal basis of the directive was vulnerable to attack due to the supremacy of internal market measures over public health within the EU Treaty. When allegations of inconsistencies with WTO Agreements were added into the debate, the resulting legal confusion introduced doubt into the minds of policymakers. Comparable arguments, despite being privately acknowledged to be baseless, had been politically effective in countering legislation in Canada and Thailand. Given the complex and often mis-understood relationship between trade and health, it is likely the industry will continue to misuse such arguments particularly in the contexts of the World Health Organisation (WHO) Framework Convention on Tobacco Control (FCTC) and emerging debates about legislation requiring cigarettes to be sold in plain packaging.

Second, the documents highlight how the institutional pluralism of the EU, by providing so many targets for lobbying, advantages well resourced corporate actors compared to poorly resourced public health advocates. The protracted time frame between proposal, adoption, passage and implementation of a directive into law, and the enlargement to 27 Member States and over 700 MEPs augments this problem, thus increasing the scope for well resourced actors to block legislation, an issue that is at the heart of the debate on the Lisbon Treaty.

Third, it could be argued that some of the Commission’s proposals on ingredients were at best vague (measurement methods, disclosure, safety testing) and at worst, potentially hazardous to health. Not only did this provide a “legitimate” reason for meetings between the Commission and TTCs, in which TTCs could then present their own data and outwardly show a willingness to cooperate in the regulatory process, it also contributed, once the TPD was implemented, to non-compliance and misinterpretation by Member States and tobacco companies. Such ambiguities in texts, coupled with
indecision or disagreement within the health community, creates opportunities for tobacco industry efforts to undermine health initiatives.

Finally, tobacco control advocates need to be alert not only to TTCs efforts to obstruct legislation being passed, but also to their actions to stall its implementation. Litigation against Member State governments is an important instrument used to achieve this.

Implications for policy and practice

1. In reviewing the TPD the Commission may wish to build on achievements to date by expanding the size of current health warnings, restricting the use of product innovations as it has the use of misleading descriptors, and exploring the role for plain or standardised packaging. Doing so would build on the items in the TPD that caused the industry greatest concern (which, along with a growing evidence base, help identify the measures of greatest effectiveness), and help limit the industry’s attempts to undermine the TPD.

2. The industry’s willingness to use arguments that it has been advised are groundless demonstrates the need for policy makers and the media to be aware of industry tactics and to treat its arguments with extreme caution.

3. The scope of arguments advanced and misappropriated by tobacco companies, particularly the use of trade and legal arguments, highlights the diverse expertise required for effective tobacco control advocacy in Europe. This in turn, and along with the points outlined below, raises the issue of appropriate funding for tobacco control groups.

4. Policy makers need to remain alert to the methods that tobacco companies use to lobby, including efforts to disguise their involvement. This requires, *inter alia*, that the declarations of interest representatives in the Commission’s voluntary register are carefully monitored and ideally made obligatory[1-2].

5. The TPD experience highlights how the industry actively seeks to and is often successful in shaping wider popular debate around tobacco control issues, proving adept at eliciting favourable media coverage and third party support. This underlines the importance of the health lobby pro-actively engaging the media, trade unions and other potentially involved parties to ensure they have accurate information on policies and likely impacts.
6. The industry will exaggerate economic arguments (see section 4.3.3) and its ability to do so has been enhanced by the implementation of a systematised approach to impact assessment that favours business interests. Policy makers must be aware that evidence of economic impacts submitted by the industry maybe highly misleading.

7. Difficulties with scientific and technical aspects of the TPD demonstrate that successful product regulation requires greater scientific consensus on such issues and ongoing access to independent expert advice during policy development.

8. The strong position taken by Commissioner Byrne and his staff was key to the directive’s success, highlighting the importance of strong leadership to successful health policy within the EU and the need to successfully implement Article 5.3 of the FCTC across Europe in order to protect public policy from inappropriate industry influence.

9. The national politics of tobacco control within member states are crucial, and require that health advocates hold governments effectively to account, including via curtailing the influence of the industry. This remains a key issue in Germany.

10. Understanding divisions between individual tobacco companies could be advantageous to tobacco control. Future policy development could be facilitated by detailed understanding of their respective positions and priorities.

11. That the overturning of the ban on misleading descriptors on products for export contained within the TPD and the problems with enforcement and implementation of some aspects of the TPD may be in part attributable to draftsmanship, demonstrates the need for legislation to be carefully drafted and repeatedly checked following contested amendments.

12. Such limitations notwithstanding, the TPD has contributed significantly to the international development of product regulation, not least by strengthening the EU position on this issue in FCTC negotiations and providing a basis which the FCTC can now take forward.
1 INTRODUCTION

“While Blak was still speaking, Fernandez walked up to him and promptly bit him on the ear: blood was visible.”

This account, by an observer at a December 1997 plenary session of the European Parliament (EP) on the Tobacco Products Directive (TPD), describes Mr Fernandez’s (Portuguese MEP) reaction to Mr Blak’s (Dutch MEP) suggestion that Fernandez was in the pay of the tobacco industry. Despite events such as this, the passage of the TPD was relatively straightforward, certainly compared with that of the Tobacco Advertising Directive which was first proposed in 1989, finally agreed in 1998 almost 10 years later, only then to be annulled by the European Court of Justice (ECJ) in October 2000[3]. The TPD, on the other hand, was enacted despite concerted efforts by the tobacco industry to derail it. Nevertheless, an understanding of what transpired as the TPD passed through the legislative process is essential for a number of reasons.

First, apart from three updated tobacco taxation directives, the TPD is, along with the Tobacco Advertising Directive (2003), one of only two major tobacco control directives passed by the EU in the last 15 years (see Appendix 1). Second, other than work on the annulled tobacco advertising directive[4], there has been little detailed analysis of the industry’s strategic objectives and working methods at EU level. Yet transnational tobacco companies (TTCs) have challenged the legality of every major EU tobacco control policy (except those on taxation) since 1992: the TPD alone was subject to at least five legal actions. Third, understanding how the tobacco industry responded to the TPD will have important implications for current debates on tobacco control policy, especially in relation to the current review of the TPD, debates around generic packaging and the development and implementation of the Framework Convention on Tobacco Control (FCTC). Above all, this is an important public health research area since tobacco use is the single largest cause of avoidable disease and premature death in the EU[5].

The TPD (2001/37/EC) was formally proposed by the European Commission on 16 November 1999[6] and came into effect on 5 June 2001. It was therefore being negotiated while the Tobacco Advertising Directive was being challenged in the ECJ (October 1998 to October 2000). The TPD replaced weaker legislation dealing with the tar yield of cigarettes[7], sale of oral tobacco[8] and labelling of tobacco products, while also introducing new measures on ingredient and additives disclosure and bans on misleading descriptors such as ‘light’ and ‘mild’[9]. The main provisions of the final 2001 directive were:

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a Blak’s suggestion had been based on Fernandez’s earlier speech fervently opposing the proposed legislation.
b The FCTC is the first global public health treaty negotiated under the auspices of the World Health Organization (WHO) and provides an internationally co-ordinated response to combating the tobacco epidemic. It was adopted by the World Health Assembly on 21 May 2003 and entered into force on 27 February 2005. It has since become one of the most widely embraced treaties in UN history. By June 2009, it had 164 Parties.
• Application of ceilings for tar (10mg), nicotine (1mg) and carbon monoxide (10mg) on all cigarettes marketed or manufactured in the EU (including those exported from the EU (article 3));
• Measurement of tar, nicotine and carbon monoxide using specified International Organization for Standardization (ISO) standards and approved laboratories (article 4);
• Development of testing methods for other substances to assess health effects and addictiveness (article 4);
• Labelling of cigarette packs with the tar, nicotine and carbon monoxide yields (article 5)
• Enlargement of health warning labels to cover 30% of the front and 40% of the back surface area of each pack with warnings and yields to be in black type on white background (article 5);
• Product marked with batch number for traceability (article 5);
• Disclosure of all ingredients by brand name and product type, including reason for inclusion and toxicological data on ingredient in burnt and unburnt form, and any addictive effects (article 6);
• Prohibition of the use of misleading descriptors such as ‘mild’ and ‘lights’, (including trademarks and figures) on all tobacco products (article 7);
• Prohibition of the sale of oral tobacco (article 8);
• The Commission to propose a common list of ingredients (article 12);
• Pending publication of this list, member states may prohibit the use of ingredients which increase addictive potential of tobacco (article 13).

Further details of the provisions assimilated into the final directive are given in Appendix 2. It is worth noting that, following litigation by the TTCs, these final provisions differ from those originally proposed in one significant way: the ban on misleading descriptors (article 7) does not apply to products manufactured for export, despite this having originally been intended.

This report analyses the tobacco industry’s efforts to influence the provisions of EU TPD (2001/37/EC)[10]. In particular, it aims to:
• Assess the industry’s perception of the threat posed by the directive, and how this varied across companies;
• Examine the tactics employed by the tobacco industry to influence the directive;
• Identify generic lessons for the EU institutions and the public health community around how the tobacco industry seeks to influence policy.
2 BACKGROUND

2.1 The emergence of a public health competence in the EU Treaties

The European Economic Community (EEC) was established in 1957 when six countries ratified the Treaty of Rome[11]. Subsequent accessions and political and economic integration have seen the EEC expand and transform into a 27 member Union.© Since the prime purpose of the EEC (and later EU) was to foster economic growth, the Treaties were constructed to promote trade and advance economic integration, and the initial treaties did not contain any general legal basis for public health measures. Subsequent treaties have, however, progressively rectified this omission.

In 1991 the Treaty of Maastricht introduced a new competence in public health. Article 3(o) stipulated that the Community should contribute to the attainment of a high level of health protection and Article 129 identified two areas for Community action: disease prevention and health protection. The scope for action in the field of public health was however highly constrained, being limited to adoption of non-binding recommendations and providing “incentives” for action. Harmonisation of laws and regulations of the Member States for the purposes of public health protection was specifically excluded.

The 1997 Treaty of Amsterdam (implemented May 1999), in Article 152 (which amended Article 129), extended slightly the EU’s competence in the field of public health by requiring that a high level of health protection be “ensured in the definition and implementation of all Community policies and activities”[12-13]. This subtle change in wording meant that new measures adopted by the Community should ensure (rather than merely contribute) to a high level of health protection. However, while these Treaty amendments required that public health considerations should be incorporated in legislation designed for other purposes it remained, as it does to this day, impossible for the EU to legislate solely to achieve public health goals[14].

Most European public health (including tobacco control) legislation has therefore been based on other articles in the Treaty – those governing the internal market, notably Article 100A (later Article 95). Article 100A, first introduced in the 1986 the Single European Act and amended slightly as Article 95 in the Amsterdam Treaty, requires the Commission, when taking internal market measures, to take as a base for its proposals, “a high level of health protection” (see Appendix 4). Tobacco control measures have had their legal basis in this article, as different national legislations must be synchronised to prevent the imposition of barriers to trade and thus to enable the smooth running of the internal market [15].

© The European Union (EU) was officially created through the Maastricht Treaty agreed in 1992
2.2 Conflict between protecting the single market and health protection

The appropriateness of this approach, namely the Commission’s use of internal market provisions to enact public health measures, has been disputed, most notably by the tobacco industry and its allies. This is perhaps best illustrated by the case brought against the advertising ban (98/43/EC) by the German government and four tobacco companies, which led to its annulment by the ECJ in October 2000[15-16]. The ECJ ruled that the EU advertising directive was ultra vires (i.e. exceeded its legal basis) as an internal market measure and disproportionately restrictive[3] because it did not facilitate the movement of goods or equalise the conditions of competition in the tobacco advertising market, but essentially eradicated that market[17]. This decision confirmed that Article 95 applied only to the internal market, so that restrictions on advertising that had no trans-frontier aspects fell outside its scope. Importantly, however, the Court accepted the legitimacy of restricting advertising under the Treaty provisions and, in its ruling, even set out the elements that would be legal in any future legislation.

This case also highlighted the significance of key legal principles enshrined in EU law, proportionality and subsidiarity. The subsidiarity principle is intended to ensure that the Community takes action “only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States”[18]. It is linked with the principle of proportionality: “action by the Community shall not go beyond what is necessary to achieve the objectives of this Treaty”[18].

2.3 EU policy making process

EU decision-making processes vary according to which article of the Treaty is being used and the policy in question. In the case of the TPD, the directive was proposed by the European Commission’s Directorate General (DG) responsible for Health and Consumer Protection (known as DG SANCO). Following inter-service consultation with other Commission Directorates, the draft directive is then debated, amended, and ultimately agreed through a process of co-decision by the EP (representing Europe’s citizens) and the Council of Ministers (CoM) (representing the governments of Member States). Within the EP the draft legislation is debated in Committee, in this case the Committee on the Environment, Public Health and Consumer Policy, which appoints a rapporteur to report on the proposal and oversee its progress. Other committees, in this instance the EP’s Legal Affairs and Internal Market, and Industry, External Trade, Research and Energy Committees (which also appoint rapporteurs), give opinions, as do two external consultative bodies comprising, respectively, representatives of socio-occupational interest groups and regional administrations, the European Economic and Social Committee (EESC) and Committee of the Regions (CoR). The Council employs

\[d\] Also known as ENVI or the Environment Committee and referred to hereinafter as the Environment Committee

\[e\] Also known as JURI and referred to hereinafter as the Legal Affairs Committee

\[f\] Also known as INDU and referred to hereinafter as the Industry Committee
qualified majority voting, a system in which, at the time the TPD was being discussed, gave Germany, the United Kingdom (UK), Italy and France the largest weighting (10 votes each). The draft passes through several readings in the CoM and the EP where changes can be made to the text. The aim is to achieve a ‘Common Position’ which is then considered by the Commission. Where consensus is not reached between the Council and Parliament, the proposal is referred to a Conciliation Committee (made up of delegates from each institution) for a final attempt to agree a joint text[19]. (For further details of these procedures see Appendix 3 and for progress of the TPD through the EU institutions see Section 2.5).

### 2.4 Background to the Tobacco Products Directive (TPD)

Although the TPD included new measures, it also revised existing directives on cigarette labeling and yields (Directives 89/622/EEC, 92/41/EEC, and 90/239/EEC). The need for updated legislation to provide greater clarity had become apparent following industry efforts to undermine the existing directives through legal challenges to their transposition in three Member States[20-23] and inappropriate application of labelling requirements (for example the use of reflective gold lettering which made warnings difficult to read)[24]. Analysis of internal industry documents, released by whistle blowers and through litigation, had also revealed the industry’s use of additives in cigarettes, including ammonia[25-27] to enhance addictiveness, and its attempts to mislead consumers into believing that so called “light” or “mild” cigarettes conferred some health benefit[27-28], all of which highlighted the need for regulation in this area (interviews with EU legislator in August 2006 and September 2008).

A critical point came in October 1996 with the proposals of the High Level Cancer Experts Committee on cigarette labeling and content[29] (see Table 1 for timeline). This prompted the Commission to make recommendations in its December 1996 Communication for action to reduce tobacco consumption (COM(96)0609)[30]. Between 1997 and 1999, widespread consultation with Member States (to examine existing national legislation and gauge the degree of support for further legislation)[31-32] was undertaken, as well as with the tobacco industry and non-governmental organisations (NGOs)[31], alongside the formal inter-service consultation (obtaining opinions from other DGs). Having received generally supportive submissions from Member States (interviews with EU legislator in August 2006 and September 2008) and identified discrepancies in national legislation⁹, the Commission felt justified in recommending next steps to the Parliament in September 1999[32]. This led to the formal TPD proposal, which was submitted to the Parliament and Council (as COM (1999)594 final) on 16 November 1999[6].

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⁹ Such discrepancies require the Commission to take action under Article 95 (100A) to harmonise the market in cigarette products.
<table>
<thead>
<tr>
<th>Year</th>
<th>Legislation</th>
<th>Description</th>
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<tbody>
<tr>
<td>1989</td>
<td>Labelling Directive 89/622/EEC</td>
<td>Tar and nicotine yield to be printed on the side and a health warning on the front of each cigarette pack in a clearly legible print with contrasting background. Each warning to cover 4% of the appropriate surface, 6% for countries with two official languages &amp; 8% for countries with three official languages. Health warning to be applied also to tobacco products other than cigarettes but without specific criteria regarding clarity and legibility.</td>
</tr>
<tr>
<td>1992</td>
<td>Labelling and smokeless tobacco directive 92/41/EEC</td>
<td>Amended Directive 89/622 by introducing a wider range of warnings for cigarettes and other tobacco products, and each warning in each language to cover at least 1% of the total surface of the unit packet for products other than cigarettes. Marketing of certain tobacco products for oral use banned.</td>
</tr>
<tr>
<td>October 1996</td>
<td>Recommendations of the High Level Cancer Experts Committee</td>
<td>Called on the EU to, inter alia, regulate cigarette content through permitted additives in cigarettes which were proven to be non-toxic in burnt and unburnt form; set maximum yields for tar, nicotine and carbon monoxide; and strengthen labelling.</td>
</tr>
<tr>
<td>December 1996</td>
<td>COM(96)0609</td>
<td>Communication from the Commission to the Council and the EP on the present and proposed Community role in combating tobacco consumption: set out policy options at Community level based on Helsinki recommendations</td>
</tr>
<tr>
<td>1997-9</td>
<td>Commission consultations</td>
<td>Commission analysis of existing legislation and degree of harmonisation at Member State level, inter-service consultation and consultation with stakeholders (including tobacco industry and NGOs)</td>
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</table>

This interest in product regulation built on limited practice in Member States and emergent international efforts to secure ingredients disclosure. Innovative legislation in Thailand (1992) and Massachusetts, USA (1996) required by-brand ingredient disclosure but was heavily contested by the tobacco industry, with the result that Thailand’s proposed legislation was critically undermined and that in Massachusetts ruled invalid on the grounds that its disclosure of trade secrets ingredients was unconstitutional[33-34]. Canada introduced extensive Tobacco Reporting Regulations in 2000[35] which require, inter-alia, detailed reporting on product composition and emissions. These regulations have been identified by WHO an example of international best practice[36].
Such initiatives reflected increasing awareness of both the inadequacies of earlier efforts to regulate products (which had focused only on tar and nicotine measurement) and the weaknesses in existing testing methods. The ISO method, the most widely used measure and the one proposed in the TPD to measure tar, nicotine and carbon monoxide levels, did not reflect the actual amount of tar and nicotine inhaled by human smokers and was widely recognised as misleading[37]. Yet modified-ISO test methods used in Massachusetts and Canada also had limitations and were not, at that time, widely accepted[38-39]. The public health gains from lowering tar and nicotine levels and labelling products based on ISO measured levels were therefore heavily contested[40-42]. A key issue was that basing labels on the misleading levels of tar, nicotine and carbon monoxide produced by ISO testing might, as the industry had intended in the design of “light” cigarettes[43-44], lead smokers to mistakenly believe that shifting from high- to low-tar brands would confer some health benefit, thus encouraging them to make this shift rather than quitting[40]. Consequently, recent discussions have considered removing yield labels from cigarettes altogether[39].

2.5 The passage of the TPD

The passage of the TPD through the European institutions involved the co-decision procedure described above. Thus the directive was adopted with 44 amendments at the Parliament’s first reading in June 2000, and received a qualified majority in the subsequent Council meeting, with a common position adopted on 31st July 2000. It was then returned to the Parliament for its second reading in December 2000 (for details see Table 2). However, the Commission and the Council were then unable to accept all of the Parliament’s second reading amendments, prompting a conciliation process. In early 2001 a compromise text was produced, which was approved by the Parliament and Council in May 2001 and signed into law in June of that year.
<table>
<thead>
<tr>
<th>Year</th>
<th>Date</th>
<th>Key Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
<td>16 November</td>
<td>The Commission (DG Sanco) adopts the proposal for a directive on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products[45]</td>
</tr>
<tr>
<td>2000</td>
<td>7 January</td>
<td>Submission of draft directive to EP and CoM</td>
</tr>
<tr>
<td></td>
<td>21 January</td>
<td>Proposal submitted to Environment Committee as responsible committee (rapporteur: Jules Maaten)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Proposal submitted to Legal Affairs Committee for its opinion (rapporteur: Kurt Lechner)</td>
</tr>
<tr>
<td></td>
<td>14 February</td>
<td>Proposal submitted to the Industry Committee for its opinion (rapporteur: Werner Langen)</td>
</tr>
<tr>
<td></td>
<td>23 March</td>
<td>Meeting of the Environment Committee to discuss proposal</td>
</tr>
<tr>
<td></td>
<td>29 March</td>
<td>Opinion by EESC[46]</td>
</tr>
<tr>
<td></td>
<td>12 April</td>
<td>Opinion by the CoR[47]</td>
</tr>
<tr>
<td></td>
<td>17 April</td>
<td>Meeting of Environment Committee to discuss proposal</td>
</tr>
<tr>
<td></td>
<td>16 May</td>
<td>Opinion by the Legal Affairs Committee[48]</td>
</tr>
<tr>
<td></td>
<td>24 May</td>
<td>Opinion by the Industry Committee[48]</td>
</tr>
<tr>
<td></td>
<td>25 May</td>
<td>Final meeting of Environment Committee; draft directive adopted with strong majority</td>
</tr>
<tr>
<td></td>
<td>30 May</td>
<td>Report by Environment Committee[48]</td>
</tr>
<tr>
<td></td>
<td>14 June</td>
<td>EP 1st reading vote, adopted by strong majority with 44 amendments</td>
</tr>
<tr>
<td></td>
<td>28 June</td>
<td>Commission accepts most EP amendments, but makes some changes to draft directive and transmits it to the EP and CoM</td>
</tr>
<tr>
<td></td>
<td>29 June</td>
<td>CoM (European Council of Ministers) meeting, adopts draft directive with qualified majority. Adopted 17 amendments which had been proposed by EP (15 of which the Commission had also accepted and 2 of which they had rejected), also made further changes</td>
</tr>
<tr>
<td></td>
<td>31 July</td>
<td>CoM’s formal adoption of common position[49] &amp; directive returns to EP for second reading</td>
</tr>
<tr>
<td></td>
<td>16 October –</td>
<td>Environment Committee considers common position</td>
</tr>
<tr>
<td></td>
<td>21 November</td>
<td></td>
</tr>
<tr>
<td></td>
<td>22 November</td>
<td>Environment Committee submits draft directive to EP[50]</td>
</tr>
<tr>
<td></td>
<td>13 December</td>
<td>EP 2nd reading; vote adopted with 32 amendments to the common position</td>
</tr>
<tr>
<td>2001</td>
<td>16 January</td>
<td>Commission gives opinion on EP’s draft directive. Can only accept 22 of the 32 amendments and suggests conciliation procedure</td>
</tr>
<tr>
<td></td>
<td>6-27 February</td>
<td>Conciliation procedure[51]</td>
</tr>
<tr>
<td></td>
<td>27 February</td>
<td>Conciliation Committee agrees joint text[52]</td>
</tr>
<tr>
<td></td>
<td>14 May</td>
<td>CoM at 3rd reading approves joint text[53]</td>
</tr>
<tr>
<td></td>
<td>15 May</td>
<td>EP at 3rd reading approves joint text[54]</td>
</tr>
<tr>
<td></td>
<td>5 June</td>
<td>Joint signature by EP and CoM</td>
</tr>
</tbody>
</table>

Source: information mainly taken from [http://ec.europa.eu/prelex/detail_dossier_real.cfm?CL=en&DosId=152261#292266](http://ec.europa.eu/prelex/detail_dossier_real.cfm?CL=en&DosId=152261#292266)
3 METHODS

This report is based on a qualitative analysis of previously confidential industry documents which were released into the public domain following litigation in the USA. The documents used were retrieved from online searches on specialised databases established to facilitate public access to these documents. The search strategy was developed with guidance from existing literature on research techniques for industry documents[55-56]. Broad initial terms such as “product directive” and “EU” were used to inform subsequent, more focused searches based on names, events and terminology identified in the broader searches. Boolean operators were used where possible to refine searches. The majority of documents retrieved were in English but some relevant documents were in German. Where the authors have translated documents from another language into English, this is stated.

Relevant documents were downloaded into an EndNote library and analysed following a form of thematic analysis adapted for company documentation by Forster[57]. To improve reliability and validity, document data were triangulated with other sources such as semi-structured interviews with relevant individuals and other industry documents. Additionally, secondary sources were searched via the internet, including Europa for official publications from the EU institutions, Nexis for media reports, websites of lobbying, consultancy and trade organisations cited in the documents; tobacco industry journals and public health NGO websites. By looking for both corroborating and conflicting evidence, such an approach helps overcome potential inadequacies and pitfalls in document-based research. Key informants for interviews were identified through existing contacts known to the research team, an analysis of documents (as outlined above) and by asking initial interviewees for recommendations. All potential interviewees were approached by email and sent in advance a participant information sheet, which outlined the background and aims of the research project as well as the provisions for confidentiality and consent.

Preliminary document searches and two interviews were undertaken between June and August 2006, following approval from the London School of Hygiene and Tropical Medicine Ethics Committee. At that time searches were conducted on the BAT Documents Archive\(^h\) for BAT documents and the Legacy Tobacco Documents Library\(^i\) for PM and other company documents. More comprehensive searching, that allowed for the addition of new documents to these online archives after August 2006, was carried out in these two online libraries between June and October 2008 (although the two libraries were combined in July 2008 so searches after this date were all undertaken in the combined library). During this second period of investigation, five

\(^h\) [http://bat.library.ucsf.edu](http://bat.library.ucsf.edu)
\(^i\) [http://legacy.library.ucsf.edu](http://legacy.library.ucsf.edu)
further interviews were carried out, following approval by the Research Ethics Committee at the University of Bath’s School for Health, all of which were recorded and transcribed. Details of how to access the online document databases directly are given in Appendix 5 for those wishing to search for documents themselves.

4 RESULTS
4.1 Document characteristics

Approximately 6000 documents were retrieved by the searches and assessed for relevance. 905 proved relevant and were analysed in detail to inform the findings presented in this report.

Most of the documents obtained were from BAT, PM and RJ Reynolds (RJR), with the majority of documents on lobbying tactics from BAT. This likely reflects a number of issues including the nature of the document collections[58-59]. First, only tobacco companies operating in the USA were subject to the litigation that led to the release of documents. Thus while it was clear, both from documents and interviews, that other Europe-based companies (e.g. Imperial and Reemstma), were also active in lobbying against the directive, their documents do not feature directly. Second, BAT, a UK-based company, was generally more candid in its documents than the USA-based corporations[59]. Third, BAT had more to lose than PM and fourth, around the time the TPD was being developed and negotiated, RJR was itself negotiating a takeover deal with Japan Tobacco and may thus have been less active in lobbying than the other companies.1

It is also notable that of all the EU member states, Germany and the UK feature most heavily in the documents. This may simply represent their importance within the CoM, the prominence of British and German companies within the global tobacco industry and, in Germany’s case, the close relationship between the tobacco industry and government[60]. But it may also be an artefact of the document collections. BAT is registered in the UK and, despite having many affiliate and subsidiary local operating companies, the documents obtained through litigation come only from BAT's UK offices and from Brown & Williamson, their former USA affiliate. The BAT documents therefore give details of these subsidiaries via their correspondence with the UK office, thus weighting the evidence towards the UK. In addition, BAT, like the other tobacco companies, has a major subsidiary in Germany and this, along with the extensive correspondence between the Verband der Cigarettenindustrie (VdC) and various company headquarters, may have weighted the evidence towards Germany.

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1 In 1999 RJR sold its international tobacco business to Japan Tobacco, creating Japan Tobacco International (JTI).
4.2 Overview of industry concerns and responses

4.2.1 Company and pan-industry responses and concerns

The Commission consultations and proposals for further legislation, like the draft TPD that followed, caused significant alarm within the tobacco industry and led to an active, high level response[61-65]. Detailed strategies for contesting the directive were developed carefully both by individual companies and various pan-European membership organisations (see Table 3), with lobbying targeted according to the audience and the stage of the directive’s legislative passage[66-69]. Of the membership organisations, the Confederation of European Community Cigarette Manufacturers (CECCM) and the national manufacturing associations (NMAs)[70-71] were particularly active[66, 72-75].

Although individual companies varied somewhat in their response to the directive’s contents, all were concerned by the ban on misleading descriptors (article 7) and agreement was reached to “defend the use of descriptors by all means”[76]. They were also united in their concern about the proposed yield reductions, particularly for carbon monoxide (article 3), the requirement to provide brand-specific ingredients/additives disclosure and toxicological data (article 6) and the large size of the proposed health warnings requirement (article 5)[66, 77-79, 76]. Companies with major European manufacturing bases, unlike PM, were particularly alarmed by the proposed application of articles 3 and 7 (yields and misleading descriptors) to products manufactured for export[77, 80], erroneously referring to this aspect as the “indirect export ban” or “de facto export ban”[81-82]. BAT described these two export provisions as the “most critical”[66].

Table 3: Key pan-European tobacco industry organisations involved in lobbying

<table>
<thead>
<tr>
<th>Umbrella organisation</th>
<th>Membership and role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confederation of European Community Cigarette Manufacturers (CECCM) established 1998</td>
<td>Represented the collective political interests of the major companies (at that time, BAT, PM, Imperial, Gallaher, Japan Tobacco International (JTI), Reemstma, RJR and Rothmans) and their National Manufacturers Associations (NMAs) in Europe.</td>
</tr>
<tr>
<td>Confederation Europeenne des Dettaillants en Tabac (CEDT)</td>
<td>Promoted the commercial interests of over 350,000 tobacco retailers in Europe.</td>
</tr>
<tr>
<td>European Smoking Tobacco Association (ESTA)</td>
<td>Represented small to medium sized manufacturers, distributors and importers of fine-cut (rolling), pipe, chewing and nasal snuff tobacco.</td>
</tr>
<tr>
<td>European Carton Makers Association (ECMA)</td>
<td>Represented the national carton associations in Europe.</td>
</tr>
<tr>
<td>Federation Europeenne des Transformateurs de Tabac (FETRATAB)</td>
<td>Comprised the majority of tobacco processors in Europe, including the national associations of processors of four of the major European tobacco leaf producing countries: Italy, Spain, Greece and France. FETRATAB represents and defends the interests and activities of European tobacco processing and trading companies.</td>
</tr>
<tr>
<td>Groupement des Industries Europeennes du Tabac (GITES)</td>
<td>Represented smaller companies, particularly state monopolies, including the Greek Tobacco Industries, Altadis (formed from the French Societé Nationale d'Exploitation Industrielle des Tabacs et Allumettes (SEITA) and Spanish Tabacalera merger), Austria Tabak, Ente Tabacchi Italiani and Heintz Van Landewyck (Luxembourg)</td>
</tr>
<tr>
<td>Tobacco House</td>
<td>Association of various European tobacco interests including retailers, farmers, processors and companies in Europe (see Box 1)</td>
</tr>
</tbody>
</table>
4.2.2 Initial cohesive response

In response to the threat of further regulation signalled by the Commission’s December 1996 Communication (COM (96) 0609)[83], CECCM’s new Chairman, Wilfried Dembach, previously of RJR[84], wrote to CECCM Board members, suggesting the EU was “determined to destroy our markets” and “produce profound societal change in respect of smoking”[85]. Dembach suggested this required a comprehensive and cohesive industry response, calling for goodwill in establishing a common position. He also outlined the need for a new corporate culture for CECCM, most notably a more proactive and prominent role in public affairs outlining that:

“If we cannot compete in the battle for public opinion then we will invariably lose out in the political arena. If we fail to influence the institutions positively then we will be left defenceless ….”[85].

In line with Dembach’s calls for a united response[85], the individual companies and their joint organisations adopted a relatively unified initial stance on the 1998 consultation[31]. They established pan-industry working groups to develop argumentation against key aspects of the proposals[86, 66, 87] and collectively lobbied against them claiming, for example, that there was no rationale for such European tobacco control measures, which were instead a matter for Member States, and that the legal basis was suspect[88-92]. Dr Ernst Bruckner, head of the German cigarette industry association VdC, wrote a rallying letter to his “friends” in the industry:

“The Commission pursue a policy towards tobacco products which ultimately aim at their total elimination… a cold prohibition….We all should make a big united effort to fight this policy”[70].

4.2.3 Emergent divisions in the industry

Although the documents suggest that the industry was united in its initial responses to proposals for a directive, splits later became apparent. Tensions between partner organisations in CECCM coincided with the creation of “Tobacco House” in 1998. Tobacco House was a venture spearheaded by PM, Société Nationale d’Exploitations Industrielle des Tabacs et Allumettes (SEITA), International Union of Tobacco Growers, Federation Europeenne des Transformateurs de Tabac (FETRATAB) and Confederation Europeenne des Detaillants en Tabac (CEDT) (but notably, not BAT) to bring together a far broader group of tobacco sector interests than present in existing pan European organisations[93], a move seen as strategically advantageous at a time when the industry was under pressure[94](see Box 1).

¹ The then French tobacco monopoly.
Tobacco House was created to bring together all European tobacco industry groups with the objective of: “restoring the legitimacy and credibility of the entire tobacco sector and becoming a reasonable and constructive partner of the European Institutions... developing consensus...and communicating such consensus to the European Institutions.”[93]. The documents however suggest that the priorities of most of CECCM’s powerful members diverged from those of Tobacco House’s smaller partners, such as GITES and the European Confederation of Tobacco Retailers (CEDT). Whereas CECCM and its members wanted to preserve the independence of participating organisations by bringing all partners together but not forcing them to speak with one voice[95-98], the smaller partners favoured a strong single entity.

David Davies of PM acknowledged the smaller companies’ concern that Tobacco House would merely become a “forum for CECCM”[94]. He therefore called for CECCM to do everything possible to realise the Tobacco House project, noting the strategic advantage of “a platform which unites all....and enables the entire industry to speak with one voice ......at a time when we will be facing severe pressure in relation to a number of vital issues such as the product and packaging regulation initiatives”[94].

Tensions between Tobacco House members and within CECCM itself continued, some in relation to the TPD. Documents suggest that conflict was most apparent between PM and European-based TTCs[99]. For example, PM disagreed with Reemtsma (a German tobacco company, now part of Imperial Tobacco) over the candidature for Presidency of Tobacco House, with Gallagher (an Ireland based company, now part of JTI) on the issue of tar banding levels[76] and with BAT on the tone of speaking notes for a presentation to the Commission on the proposed directive. In the latter case, PM complained that BAT’s submission was far too negative and confrontational[100], presenting the industry in its “traditional arrogant mode”[101]. BAT objected to any counter-proposals to the directive, claiming these would imply industry acceptance of its legal basis and endanger future legal action against the directive[102]. This “impasse”[103] was significant enough to warrant serious discussion about disbanding CECCM, and a further meeting was arranged to resolve the conflict[74]. Ultimately CECCM did release an agreed statement accommodating both BAT and PM’s positions:

“We are of the opinion that the draft [TPD] is fundamentally without legal base. All of our further comments are subordinate to this position”[104].

Tensions then heightened when PM reportedly contradicted an agreed CECCM lobbying position at the UK Tobacco Manufacturers Association (TMA) reception at the Conservative Party Conference in 2000, telling Members of Parliament that the application of yield and labelling requirements to exports was not important. This seriously concerned Imperial and Gallaher (which dominate the UK market), and David Swan, the President of the TMA, described as “outraged” by
PM's actions and wrote a formal letter to a member of the House of Commons to correct these statements and to apologise for any confusion[105].

Documents and interviews suggest that the tensions were a product of differences in individual company positions and the resulting risks posed by legislation. PM's status as market leader in Europe would, for example, be more secure after the EU advertising ban, which would constrain other companies’ ability to compete for market share (interview health lobbyist, August 2006). Plus, unlike other companies, PM had “negligible” manufacturing in Europe for export, making the export provisions far less of an issue for PM[106]. BAT sought support from Reemstma by stressing that the directive disadvantaged “EU companies against non-EU multinationals”, i.e. PM[107, 99]. Moreover, PM's strategic repositioning[108-109] was more advanced than that of the other TTCs, and a conciliatory approach was in line with its ostensible transformation into a socially responsible corporation[110]. Thus while PM privately acknowledged the risks posed by product regulation[111], it outwardly promoted a strategy of “constructive engagement: openness, societal alignment, listening and dialogue”[112], acknowledging the need for regulation[77, 110].

PM's efforts to portray itself as a responsible company were apparent in a tripartite policy debate arranged by the Rapporteur for the directive in the EP. David Davies, Vice-President of PM Corporate Affairs Europe, after hearing health lobbyist’s presentations, stated that he agreed with almost everything that was said and was in favour of “responsible regulation” (interview health lobbyist, August 2006).

BAT and other companies, in contrast, were more exposed to the directive’s impact due to their substantial EU manufacturing base. They assumed more aggressive posturing, with BAT stating:

“…we should act immediately to build the necessary support to delay, amend or block the directive. The focus of our efforts will be on the legal base and articles 3 and 7”[77].

These divisions led BAT to seek support outside the traditional networks of National Manufacturing Associations (NMAs) and CECCM, believing these to be “weakened by diversity of members”, namely the presence of PM[65, 107]. By September 2000 JTI recognised that, although consensus was ideal, it had been difficult to achieve and the industry was left without a strong, united position[113]. Such evidence of divisions among companies was consistent with observations made by Commission officials, who noted that BAT, JTI and Reemstma were aggressive in their conduct, which they contrasted with PM’s polite engagement in dialogue (interviews with Commission civil servants, August and September 2008). Nevertheless, throughout the process CECCM continued its efforts to maintain cohesion and consensus amongst its members[114].
4.3 Industry argumentation

The industry quickly developed argumentation against the directive which can be categorised into four broad areas: community competence, trade, economic, and scientific/technical (Table 4). As explored below each argument was carefully directed to the audience most likely to be swayed by its message.

4.3.1 Community competence

Initially, in response to the 1998 consultation, the industry tried to negate the need for further legislative measures by claiming that harmonisation had already been completed in the areas of tar yields and labelling[88]. In relation to ingredients, while recognising the absence of harmonising EU legislation and differences in member state provisions in this field, the industry refuted the Commission’s claim that these hindered the operation of the internal market[88, 115, 69]. By contrast, in positions advanced to the Commission, CECCM members regarded lower tar and nicotine (but not the 10mg carbon monoxide) yields, more extensive ingredient disclosure and enlargement of the current 4% labels as both inevitable and incontestable[76].

<table>
<thead>
<tr>
<th>Topic area</th>
<th>Industry arguments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Community competence</td>
<td>Harmonisation already achieved in tar yields and labelling</td>
</tr>
<tr>
<td></td>
<td>No need for ingredients harmonisation as mutual recognition of national laws exists between MS, so no barriers to internal market</td>
</tr>
<tr>
<td></td>
<td>Article 95 - inappropriate legal basis</td>
</tr>
<tr>
<td></td>
<td>Article 133 – inappropriate secondary legal base</td>
</tr>
<tr>
<td></td>
<td>Article 95(3) - insufficient new scientific evidence to warrant a recast of previous directives</td>
</tr>
<tr>
<td></td>
<td>Principles of proportionality and subsidiarity breached</td>
</tr>
<tr>
<td></td>
<td>Export requirements should not feature in an internal market measure and should be dealt with as separate legislation</td>
</tr>
<tr>
<td>Trade agreement violations</td>
<td>WTO Agreement on Sanitary and Phytosanitary Measures (SPS) – risk disproportionate and need new scientific justification or risk to justify stricter regulations</td>
</tr>
<tr>
<td></td>
<td>WTO Technical Barriers to Trade (TBT) Agreement – descriptors and export provisions constitute technical barriers to trade and less restrictive means exist to achieve health protection</td>
</tr>
<tr>
<td></td>
<td>WTO Trade-related aspects of intellectual property rights Agreement (TRIPS) – breach intellectual property rights by requiring full ingredient disclosure and enlarged health warnings; undermine value of trademarks (eg Mild Seven)</td>
</tr>
<tr>
<td>Economic</td>
<td>Competitive disadvantage to European based manufacturers</td>
</tr>
<tr>
<td></td>
<td>Major cost implications of changing production requirements to comply with directive</td>
</tr>
<tr>
<td></td>
<td>Job losses &amp; loss of export earnings</td>
</tr>
<tr>
<td>Scientific</td>
<td>Lack of new scientific evidence to warrant lower yields or larger health warnings</td>
</tr>
<tr>
<td></td>
<td>Unclear definitions of additives and ingredients</td>
</tr>
<tr>
<td></td>
<td>Flawed science on addictiveness and role of additives</td>
</tr>
<tr>
<td></td>
<td>Lack of justification for ingredient and additives disclosure</td>
</tr>
<tr>
<td>Technical</td>
<td>Absence of guidance on toxicological testing</td>
</tr>
<tr>
<td></td>
<td>Lack of standardised methods for measuring additional substances</td>
</tr>
<tr>
<td></td>
<td>Current ISO methods for tar, nicotine and carbon monoxide inadequate</td>
</tr>
<tr>
<td></td>
<td>Technical difficulties in achieving tar and carbon monoxide reductions</td>
</tr>
</tbody>
</table>
The industry’s attempt to undermine the Advertising Directive, which was at this time being heard by the ECJ, had centred on contesting its legal basis[116]. It was therefore unsurprising that this argument also formed the basis of industry efforts to undermine the TPD. Indeed, even before the TPD had been formally proposed and industry legal opinions obtained, the industry planned to contest the legal basis of the proposed measures, claiming that the use of Article 95 would be “a plain abuse of the Treaty of Rome”[90]. By March 1999, while consultation on the proposals was underway, BAT identified the issue of Community competence as “the core EU battle-ground for the future of our industry”[117] and, shortly after the TPD was formally proposed, stated that agreeing the TPD text on the basis of Article 95 would “be a disaster”[118].

The industry commissioned legal opinions from several international law firms and legal scholars at different stages of the directive’s development[119-125]. Several legal arguments were examined to see if they could be utilised, including the appropriateness of Article 95 as a legal base and whether the Commission had properly established the scientific facts, as required by Article 95(3), to justify the legislation (see Appendix 4 for details of Article 95)[119-120].

Given that the Amsterdam Treaty had only entered into force in May 1999, a key issue the initial opinions addressed was whether this new Treaty provided a sufficient legal base for the proposed measures[86, 119-120, 126]. CECCM requested a written opinion to this effect from Professor Rabe, of the German law firm Gaedertz[86, 119]. Reporting in May 1999, Rabe concluded that “the courts would hold the Institutions competent under Art.95(1) EC-Treaty to adopt the legislative measures on tobacco products envisaged by the Commission.” He reiterated this opinion on the legality of the measures in a second report delivered that September[120]. With another initial legal opinion for PM drawing similarly negative conclusions for the industry, notes of a CECCM board meeting in June 1999 state “it would clearly not be possible to [legally] challenge DG5 initiatives [on yields, labelling and elimination of descriptors]” and that the possibility of challenging the additives measure “was rated to be small”[121].

Rabe did however raise one small point that later led to a challenge by BAT in the Court of First Instance (see Section 4.5). He contended that, once the community had harmonised legislation in an area of shared competence (such as health and, in this instance, cigarette labelling), a “new development based on scientific facts” (as required by Article 95(3)) would be sufficient to justify
amending existing legislation in that field. According to Rabe, such legislation would then be seen as enhancing the functioning of the internal market. This, of course, led him to make the converse point, that, had the Commission failed to establish the scientific facts required under Article 95(3) to justify a new measure, then that measure could be contested. It is noteworthy therefore, that at a later meeting with the industry, Byrne indicated that all measures in the TPD were based on scientific advice. This was deemed insufficient, however, by BAT who later brought an unsuccessful case to the Court of First Instance, seeking access to the scientific research used as a basis for the proposals.

In contrast, an opinion RJR reported verbally at a CECCM meeting (which we were unable to obtain a copy of) and another by Professor Jose Luis da Cruz Vilaça (former Advocate-General at the ECJ) in June 1999, apparently held more hope for the industry. Vilaça concurred with Rabe in many aspects but contended that, even in previously harmonised fields, the main objective of a measure based on Article 95 should be harmonisation of the internal market. Although Vilaça’s opinion only explored general issues around public health legislation in light of the newly implemented the Amsterdam Treaty, and did not comment specifically on the proposed TPD, his opinion appeared to find favour with the industry. A JTI presentation, for example, later reiterated that the main objective of a measure must be to facilitate the internal market.

Despite inconsistencies in the legal advice and having received at least one clear indication that the directive was consistent with EU law, BAT and others acting on its behalf, notably Scott Crosby of the legal firm Kemmler Rapp Böhlike, quickly sought to assert that the directive was incompatible with the EU Treaty. Such efforts were directed to the highest political levels including Ministers, the Commissioner and influential members of EP committees. Crosby in particular asserted this “fact” with absolute certainty. In February 2000, for example, in correspondence with Professor Neil MacCormick, a member of the Parliament’s legal affairs committee, Crosby argued that once the community had harmonised legislation in an area of shared competence then the community was regarded as having exclusive competence in that area. Moreover, he argued that as Article 95(4) and (5) only allow member states (rather than the community) to take action deviation from existing harmonisation measures to protect the environment or the working environment, and not for broader or other public health purposes, unless the community took action in these broader fields, it would lead to a legislative stalemate.

The industry is able to make claims of attorney client privilege and, although variably applied, this means some legal documents were unavailable to us. It is possible, therefore, that legal opinions with differing conclusions were missed.

For example, in indicating that the issues of subsidiarity and proportionality only arose once competence had been established, and that the primary objective of new measures based on Article 95 should be harmonisation of the internal market.

Vilaça disagreed with arguments, which he acknowledged had been made (including by Rabe) that the Commission, having harmonised legislation in an area of shared competence, then had exclusive competence in that area, and that Articles 95(4) and 95(5) limited Member States’ actions to the areas of environment or working environment.

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1 Rabe argued that once the community had harmonised legislation in an area of shared competence then the community was regarded as having exclusive competence in that area. Moreover, he argued that as Article 95(4) and (5) only allow member states (rather than the community) to take action deviation from existing harmonisation measures to protect the environment or the working environment, and not for broader or other public health purposes, unless the community took action in these broader fields, it would lead to a legislative stalemate.

2 The industry is able to make claims of attorney client privilege and, although variably applied, this means some legal documents were unavailable to us. It is possible, therefore, that legal opinions with differing conclusions were missed.

3 For example, in indicating that the issues of subsidiarity and proportionality only arose once competence had been established, and that the primary objective of new measures based on Article 95 should be harmonisation of the internal market.

4 Vilaça disagreed with arguments, which he acknowledged had been made (including by Rabe) that the Commission, having harmonised legislation in an area of shared competence, then had exclusive competence in that area, and that Articles 95(4) and 95(5) limited Member States’ actions to the areas of environment or working environment.
committee\textsuperscript{p}, Crosby claimed that "[a]ll its substantive provisions infringe Article 95(1) of the Treaty, some of them more than once, and the whole proposal is manifestly ultra vires"\textsuperscript{[135]}. In this and a subsequent letter\textsuperscript{[133]}, possibly picking up from comments made in Rabe's opinion\textsuperscript{q}, Crosby also attempted to describe the directive as an example of "destructive banning, albeit in stages", alleging that the Commission's ultimate intent was to eliminate tobacco products through continuous reductions in tar and nicotine and removal of additives which would render the product unpalatable. Crosby also drafted a strongly worded letter to the Secretary General of the Commission (its senior civil servant), to be copied to the member states (although it is not known if the letter, or a version thereof, was ultimately sent), claiming that BAT might seek financial compensation:

\begin{quote}
"if this directive passes into law, it is likely to cause our client [BAT] considerable prejudice. Since it does not seem that the Community has the competence to adopt the directive, this damage may be recoverable from the Community institutions. You should be aware that BAT reserves all its rights in this regard."\textsuperscript{[134]}
\end{quote}

In April 2000, during the EP's first reading, the President of the EP's Industry Committee requested the Parliament's legal advisor for an opinion on the legal basis of the directive\textsuperscript{[136]}. This request was prompted by two German MEPs who had links to the industry via the VdC\textsuperscript{[66]}. They had apparently claimed that Article 152, which gives the EU competence in public health but expressly precludes the passage of harmonising legislation, would be a more appropriate legal base\textsuperscript{[136]}. The Parliament's legal advisor confirmed that Article 95, not Article 152 was the correct legal basis\textsuperscript{[136]}.

The industry hoped that a favourable ECJ ruling on the advertising ban might assist its efforts to block the TPD during the EP's second reading or in the CoM\textsuperscript{[137, 78]}. Thus, when the advertising ban was overturned in October 2000, four further legal opinions, including another by Vilaça, were obtained for BAT to explore the effect of the ruling on the TPD\textsuperscript{[125]}. One was described as relatively pessimistic and in this instance the lawyer was asked to revisit his advice\textsuperscript{[138]}. BAT Chairman, Martin Broughton, wrote to Commissioner Byrne a few weeks later stating that the draft directive suffered from the same "legal deficiencies" as the annulled ad ban\textsuperscript{[139]}; claims dismissed by Byrne\textsuperscript{[140]}. Indeed, Byrne, a former Irish Attorney General, felt that the ECJ had been "extremely supportive" of the legal basis of the Advertising Directive in Article 95, but that its use for the non cross-border dimensions (such as bans on advertising in

\textsuperscript{p} See also Section 4.4.3.2
\textsuperscript{q} Rabe commented (page 12) that only if the directive required the product concerned (ie the cigarette) to totally change in character, for example, the tar ceiling to reduce to such an extent that a "cigarette could not be considered a cigarette any more", would it be outside the scope of Article 95(1). He did not consider this to be the case but marginalia suggest the industry saw this part of his opinion as potentially useful.
\textsuperscript{r} Basing the directive on Article 152 would of course make it unviable.
\textsuperscript{s} Despite extensive searching, these four legal opinions were not found.
cinemas, billboards and ashtrays), which were inserted by Parliament against the Commission’s advice, rendered the Advertising Directive flawed (interview with European Commission official, August 2008). Commission civil servants were therefore not discouraged by the ruling, believing the ECJ to have highlighted sufficient scope and direction to advance tobacco legislation (interview with European Commission official, September 2008).

As noted above, BAT was particularly concerned by the “indirect export ban” afforded by articles 3 (maximum yields) and 7 (misleading descriptors) in the TPD and attempted to suggest this part of the directive raised a separate legal issue[66, 141]. It argued that the export requirements were incompatible with the directive’s status as an internal market measure[141, 66], and instead comprised “extra-territorial legislation”[142, 81]. This led to the related claim that these measures were inconsistent with WTO obligations as detailed below[143]. During its second reading, the EP adopted an amendment to add Article 133, which dealt with international trade, as a supplementary legal base[140, 144] (interview with a European Commission official, September 2008, and lobbyist, September 2008).\(^1\) BAT acknowledged that Article 133 was the correct basis for export requirements but contended that such requirements could not be included within a directive dealing with the internal market and should instead be subject to a separate decision[141]. BAT wrote to Chris Kelly, Permanent Secretary in the UK Department of Health, claiming the “export ban” was “a dangerous precedent” for EU manufacturers, and implying that it might have broader ramifications for international trade[146]. By mid-December 2000, following the Council’s qualified majority and the EP’s second reading in favour of the directive, BAT recognised that its lobbying options were limited[147]. It nevertheless hoped that a legal opinion on the inappropriateness of article 133 as a supplementary legal base, presented by a “credible” voice, might yet carry weight[147].

4.3.2 Trade
Areas of possible conflict between the proposed TPD and the obligations of signatories to trade agreements, particularly those of the WTO, were identified as having potential to generate argumentation against the directive. Looking to replicate successful industry campaigns that used trade arguments to prevent the adoption of plain packaging regulation in Canada[148] and critically undermine provisions for ingredients disclosure in Thailand[33], BAT generated a legal analysis that depicted the TPD as potentially breaching WTO requirements, which could therefore expose EU member states to potentially costly disputes[149]. A May 1999 review by John Clutterbuck, of the consultancy firm Prisma (and described as an economic affairs adviser to Rothmans[150]), provided BAT with an analysis of “the relationship between WTO Agreements and potential EU

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\(^1\) The use of Article 133 was derived from a previous Council Directive on infant formulae, which permitted export to third countries only if the products complied with the directive[145].
legislation on disclosure of ingredients”[149]. This identified alleged tensions with three key WTO agreements: the Agreement on Sanitary and Phytosanitary Measures (SPS); the Agreement on Technical Barriers to Trade (TBT); and the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS).

The SPS Agreement aims to ensure the non-discriminatory application of food safety, animal and plant health regulations in WTO Member states, requiring that health measures that exceed international standards or for which such standards do not exist should be justified scientifically[151-153]. EU ingredients disclosure proposals were regarded as requiring justification with regard to articles 2.1 and 2.2 of the SPS, respectively requiring “observance of the rules on free trade” and a basis “on scientific principles, backed by scientific evidence”[149]. Though the EU had recently had a fraught experience with the WTO dispute settlement process, following its attempted prohibition of hormone-enhanced beef[151, 153], Clutterbuck regarded it as unlikely that a challenge could be anticipated in a tobacco context because it would need to be brought by a WTO member outside the EU. With the US, Canada, Australia, New Zealand and Singapore all viewed as unlikely to challenge such legislation, Clutterbuck found it difficult to identify “a country with a potential trading interest which could also launch a credible case in Geneva, challenging the science and the lack of proportionality” of anticipated EU proposals[149].

The TBT Agreement was designed to ensure that technical negotiations, standards, testing and certification procedures did not create unnecessary obstacles to trade, while recognising the right of countries to protect the environment, human and animal health[152]. The TBT agreement was depicted by Clutterbuck as offering a somewhat more promising basis for potential industry action since, under its provisions, “the difficulty of finding a country to complain” was qualified in two respects. First the Commission was required to notify WTO of the regulations, giving justification and allowing time for comment and, second, such comments could be made by companies located both inside and outside the EU, via WTO enquiry points established under the Agreement[149].

A presentation on the directive from JTI in September 2000 following the EU’s TBT notification of the directive to WTO similarly highlighted potential scope for a legal challenge under this Agreement[78]. The presentation indicated that the “Strongest Arguments of TBT Agreement Violation” related to the “Descriptors Ban” and the “Exports Ban”. The former was criticised on three counts: as being irrational in limiting information to consumers who were well used to such descriptors; as infringing TBT obligations via “[I]nterference on free flow of goods within and outside EU”; and as being more restrictive of trade than alternative measures that might be used such as banding (via which governments define terms such as “light” and “mild”) or additional health warnings[78]. The proposed measures relating to exports were similarly presented as
“Direct Interference on free flow of goods within and outside EU by limiting free trade by EU producers on World Markets”, a restriction that could not be justified with reference to a legitimate EU interest and which contradicted broader EU opposition to “[extraterritorial application of technical restrictions]”[78]. The presentation acknowledged, however, that other aspects of the directive would be “difficult to challenge legally or politically”[78].

JTI’s review identified the TBT arguments concerning the ban on descriptors (“i.e. that the ban is irrational and that less restrictive means could address the EU’s concerns”) as also applicable in the context of TRIPS, being particularly relevant “in the case of Mild Seven”[78], as a restriction on the term “Mild” could be seen as infringing JTI’s proprietary rights to its brand name Mild Seven. The TRIPS Agreement provides for the establishment of minimum standards for the protection and enforcement of intellectual property rights[153], which the TPD could be portrayed as challenging, via its provisions for larger health warnings and ingredients disclosure. In the latter context, Clutterbuck also described details of ingredients for cigarette brands as proprietary “in the same way as the recipes for soft drink cordials (e.g. Coke) are proprietary” and asserted that their disclosure would devalue owner’s rights:

“If it were to be intended by the authorities that the information, once provided by the cigarette manufacturers should be made public, those intellectual property rights would be completely abrogated. This would appear to be a clear potential breach of Art 8 of the TRIPS, and to run totally counter to the spirit of Art 7”[149].

Clutterbuck’s analysis of the relationship between WTO Agreements and prospective EU legislation concluded with the suggestion that his analysis could also be applicable in the context of labelling proposals and with the recommendation that “argumentation based on SPS, TBT and TRIPS be developed but not deployed until the time is ripe”[149].

An example of how such argumentation could be deployed was provided by BAT affiliate counsel Stephen Walzer’s account of industry interaction with Julian Ebsworth, an official in the UK Department of Trade and Industry (DTI, now Business, Enterprise, and Regulatory Reform, BERR). In April 2000 the TMA had discussed the directive with Ebsworth, who possessed “a brief legal opinion which I [Walzer] have prepared concerning illegality as far as WTO is concerned”[154]. Ebsworth was viewed as “sympathetic”, requesting “a full opinion which he will have by the end of the week”[154]. This epitomises a core strategic advantage of using trade-based arguments; they enable the focus to be shifted away from health, and the engagement of, often more powerful, officials and policymakers based in economics, trade and foreign affairs departments, as well as parliamentarians who may be less familiar with health issues (see section 4.4 below on lobbying).
The Commission responded to industry arguments about the alleged incompatibility of the directive with WTO obligations by referring to the scope for public health protection within trade agreements and by invoking precedent. A CECCM account of discussions at the EP’s Environment Committee in April 2000 cited Commission official John Ryan as describing the draft directive as favouring “non-discrimination between products that are imported, exported and manufactured in the EU”, a rule Ryan reportedly claimed to be “covered by article ‘20B’ of the WTO agreement that accepts export restrictions if related to public health protection”[145]. This assessment was allegedly supported by, inter alia, precedents from comparable EU directives addressing the export of infant formula (92/52/EEC) and harmful/dangerous products[157]. In September 2000 a Commission background note on employment and economic aspects of the proposed directive offered a similar account of WTO compatibility. Here GATT (General Agreement on Trade and Tariffs) Article 20(b) was presented as permitting trade restrictions “where they are necessary to protect human health, provided that these measures do not constitute a means of arbitrary or unjustifiable discrimination between countries”[145]. The ambiguous findings of a 1990 GATT adjudication panel that found against Thailand’s restrictions on cigarette imports[155, 158, 156] were cited as supporting the proposed measures via their recognition that “public health is a sufficient reason to justify export or import restrictions as long as they are applied on a non-discriminatory basis”[145]. A DG Trade official responsible for WTO issues also reviewed the draft directive and pronounced it as sound (interviews with EU legislator, August 2006 and September 2008).

Nevertheless, as part of international efforts to prevent the development of ingredients disclosure regulation, the tobacco industry attempted to provoke a WTO complaint under the TBT Agreement against Canada’s innovative Tobacco Reporting Regulations[35]. Representatives from Imperial Tobacco met with Ebsworth and an official from the DTI’s Trade Policy Unit after the TMA received notification of the Canadian legislation in February 2000, but they were reportedly told that “without ministerial support, which was apparently not forthcoming, DTI would not make a submission on behalf of the tobacco industry” regarding alleged trade restrictions[159]. The TMA asked the DTI to reconsider in July 2000, on the grounds that “the Canadian regulations place greater burdens on EU tobacco manufacturers than those proposed in the EC ‘Labelling’ Directive and therefore constitute a barrier to trade”[159]. The issue was then reportedly taken up by the DTI with both the

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a This apparently refers to Article 20(b) of the General Agreement on Tariffs and Trade (GATT). The scope for public health protection afforded by this article has been much disputed in the context of tobacco control[155-156].

b In the late 1980s the US Government pressured Thailand to open its market to US tobacco products. The case was referred to the GATT (the predecessor to the WTO) dispute resolution process with the US Trade Representative arguing that the import barriers and comprehensive advertising restrictions were a violation of the GATT principles. The GATT Council agreed that the ban on imports violated the trade treaty but upheld the Thai government’s right to use public health policies to protect health as long as they were applied evenly to domestic and foreign products, even where such polices (e.g. advertising bans) would make it more difficult for new foreign firms to compete with existing domestic firms.
British High Commission in Ottawa and with the European Commission[160]. A February 2001 letter from DG Trade to BAT’s corporate and regulatory affairs director Michael Prideaux, however, described Canada’s legislation as “probably compatible with WTO rules” and described the Commission as being largely unable to address such problems. The letter described the proposed TPD as having “a number of proposals which go in the same direction” as Canada’s legislation, envisaged further such international harmonisation under the FCTC and indicated that the EU would welcome consideration of “the development of multilateral guidelines on labelling” within the WTO[161], hardly the response that BAT desired.

4.3.3 Adverse economic impact

Early plans for critiquing the proposals suggested the industry should push for full consultation and for regulation to take account of the “vast socio-economic interests at stake”[88]. Over time, such economic arguments became more sophisticated, being developed against the whole directive, but particularly the export requirements[106, 139]. They were widely used, being directed, inter alia, to the UK Secretary of State for Health, other UK ministers and politicians[162-163], Commissioner Byrne[139] and European politicians[107, 162]. They proved invaluable in recruiting third parties (such as unions) to lobby on the industry’s behalf, garnering press interest[107], recruiting national politicians (including those that would not be natural industry allies) (see Sections 4.4.2 and 4.4.3.3), and in causing concern within the EP[145].

A number of arguments were raised in relation to economic impacts. First, the threat to employment and balance of trade within the EU was raised, with the directive being described as an “own goal for the EU economy” that would drive jobs and investment outside the Union[82]. Various figures were produced and widely used in lobbying[163] including a claim that in the UK alone up to 8,300 jobs were at risk[164, 106]. Others claimed that 9,000 tobacco manufacturing jobs in the EU and at least a further 30,000 jobs in companies supplying tobacco manufacturers were at risk[165]. Second, BAT argued that the directive would particularly disadvantage Europe-based manufacturers operating in international markets[143], claiming that the TPD would involve “handing a competitive advantage to the world’s largest cigarette manufacturer, US-based Philip Morris”[106]”. Third, it was claimed the technical requirements, including additional testing, yield reductions and new labelling, would impose financial costs on business that would threaten the viability of smaller firms[71, 90].

* In relation to this export issue, the Commission responded that export restrictions were needed to remove incentives to smuggle by reducing the availability of non-compliant products in countries surrounding the EU. But the Commission also considered this an ethical issue: it could not justify exporting products deemed unfit for EU populations to third countries[145] this was also the rationale behind export standards for the infant formula directive.
From the mid-1990s onwards, BAT had become increasingly interested in promoting a business orientated form of impact assessment within the EU[166-168], believing such a process would emphasise the potential costs of tobacco control legislation to business (relative to the benefits to society), thereby helping the tobacco industry to challenge tobacco control policy proposals[169-170]. Hence, simultaneously with the legislative progress of the TPD, BAT had been campaigning for business impact assessment and consultation with business to be embedded within EU policymaking processes[171-172]. This campaign had been successful to the extent that BAT, working with a broad coalition of corporations and European think tanks⁵, secured changes to the 1997 Treaty of Amsterdam which made a form of business impact assessment mandatory for all Commission proposals[170, 172]. Although clear guidelines on undertaking impact assessments were not produced until 2002 (and did not become mandatory until 1st January 2003)⁶, the industry clearly recognised the potential for impact assessment to show tobacco control legislation in an unfavourable light, and campaigned for a detailed economic impact assessment of the TPD to be undertaken from an early point in the development of the directive[89-92]. In 1998, for example, Philip Morris sent a draft of a letter intended for Dr Hunter, Director of DG SANCO, (to be authored by CECCM) to BAT staff for consideration, which, as well as suggesting the Commission was required to undertake an impact assessment of its TPD proposals, offered to assist the Commission in assessing the likely economic impacts:

“Any regulation of tobacco products should proceed from a detailed assessment of the economic and employment consequences for this significant and complex industry. CECCM is willing to assist the Commission Services in the preparation of an economic impact study pursuant to the Business Impact Assessment concerning any proposals the Commission eventually puts forward”[178].

The Commission did eventually append a brief impact assessment form to their draft TPD proposal in 1999[179] which fulfilled its obligations, given that at that time, only limited guidance on undertaking impact assessments existed (interview with European Commission official, September 2008). Perhaps unsurprisingly (given that the impact assessment the Commission produced was supportive of the TPD proposals), BAT and its representatives were not satisfied and labelled the assessment as “abysmal”[180] and “wholly misleading”[134].

BAT instead produced its own economic impact study, focusing on potential job losses in the UK[181, 164]. Entitled “Have you ever felt unfairly singled out?”[164], this depicted a lone black sheep amongst a flock of white sheep and conveyed a message that the TPD would bring

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⁵ To our knowledge, no other tobacco companies were involved in this campaign (although numerous other non-tobacco companies were)[172] and, interestingly, we found no evidence to suggest that BAT informed the other tobacco companies of this campaign, despite its clear relevance to the TPD.

⁶ These guidelines have since been updated several times, most recently in 2009 [174-177]
significant job and trade losses whilst providing no health gains. Indeed, the report claimed the directive would “wipe out” UK tobacco manufacturing and included headline figures which claimed that around 8,300 jobs were at risk at just two sites[182, 164]², even though the small print showed that the total employment in BAT’s UK factories was only 1,565[164]. Further evidence that the figures in BAT’s economic impact study may have been exaggerated included the fact that a previous report commissioned by CECCM indicated that there were only 9,927 full time jobs (0.2% of the workforce) in tobacco manufacturing in the whole of the UK[145]. Nevertheless, the study, which had been co-authored with trade unions[182] to “add more weight” [183], was widely used to lobby MPs and generate press coverage[184]. At a meeting in September 2000, the various tobacco companies involved in CECCM discussed the possibility of producing a further economic impact assessment of the TPD the following year, to be paid for via Tobacco House[185].

Simultaneously, the TMA also used the requirement for the UK government to produce a regulatory impact assessment (a business orientated form of impact assessment) of proposed legislation to claim that the costs of the directive would be substantial[186] and to again argue that proper procedures relating to impact assessment and consultation had not been followed[187-189]. In putting forward this case, the TMA appealed to the Regulatory Impact Unit (part of the Cabinet Office) and the Confederation of British Industry (CBI)aa, with which BAT had worked closely in its efforts to promote the use of impact assessment within the UK and EU[194]. A note from Chris Ogden (of the TMA) to representatives of various tobacco companies explained that the TMA had obtained from the CBI a copy of the recently produced Fair Regulation Campaign Report, which described the UK government’s consultation of the EU tobacco advertising ban as “little more than a sham…….characterised by breaches of the impact assessment rules from beginning to end” [189]. Interestingly, Ogden’s note does not acknowledge that BAT had been closely involved in establishing and sponsoring the Fair Regulation Campaign[36, 195-196], with the specific intention of maximising business influence over impact assessment in both the EU and UKbb. Despite such efforts and BAT’s extensive efforts to influence impact assessment and consultation procedures in the UK and EU[172], industry claims of inadequate consultation were promptly dismissed by the Department of Health[197-198] and documents suggest that from 2000 onwards BAT accepted it was unlikely to be able to influence the UK government using this approach[199].

² Rather misleadingly, total numbers of jobs were given rather than whole-time equivalents.

aa The CBI, as the premier organisation representing large UK companies, has long reflected the interests of the tobacco industries and BAT staff often held positions within the CBI[190]. Its current president is Martin Broughton, formerly chairman of BAT[191] and it has consistently opposed tobacco control measures such as smokefree places and increased taxation[192-193].

bb It is therefore unclear whether the other tobacco companies were aware of BAT’s involvement in the Fair Regulation Campaign and, if not, why BAT chose to keep this information confidential.
Despite BAT's very public claims about the certainty of job losses and factory closures,[139, 163-164], privately BAT was far less certain that such widespread impacts would occur[154]. Other company sources indicate that factory closures and a shift in production away from western Europe were part of an existing efficiency drive, which was totally independent of the directive and has continued to this day. For example, between 2003 and 2007, globally BAT closed 25 factories, cutting its total number of factories from 72 to 47 and reducing the countries in which BAT factories were based from 61 to 40, making over £1bn in savings[201-202]. Moreover, as the Commission observed, no massive job losses were seen following the 1990 directive limiting tar levels to 12mg[145], despite contrary predictions by the industry. Meanwhile, a CECCM report which David Byrne's office had obtained, acknowledged that there was a long-term trend towards lower employment in the tobacco industry attributable to continued improvements in labour productivity and more efficient equipment[140].

Other companies were making similar claims of economic impacts and job losses despite also closing factories[203]. It is also noteworthy that Imperial Tobacco, which was particularly vocal in arguing the economic case against the export requirements (personal correspondence Luk Joossens, August 2009), was at the time exporting vast amounts of cigarettes from its UK factories that were then illegally re-imported [200, 204]. British Customs and Excise estimate that the illicit cigarette market in the UK increased from 3% in 1996/97 to 21% in 2000/01, by which time half of the smuggled cigarettes were Regal and Superkings, Imperial Tobacco brands [200, 204]. A press notice from the House of Commons Public Accounts Committee noted that "Since 1997 there has been a marked increase in the number of cigarettes manufactured by Imperial Tobacco being smuggled back into the UK, which has coincided with a substantial increase in the company's international profits"[205].

4.3.4 Scientific and Technical Arguments

The directive’s scientific and technical elements, criticised by health and tobacco advocates alike[42, 129, 38], could be seen as the weakest components of the directive, as this section goes on to explain.

Yield reduction & disclosure

Public health groups particularly contested the effectiveness of reduced yields and yield disclosure based on discredited ISO methods[206, 40], an issue PM sought to exploit by stating that it was keen to work with public health groups to consider alternative methods[111]. The TTCs developed their own arguments centred on technical limitations[71, 207-208, 111, 79, 78, 209]. PM and JTI were particularly vocal on the tar and carbon monoxide ratios, claiming that a tar limit of 10mg was
technically incompatible with a corresponding carbon monoxide limit of 10mg[111, 79, 78]. The TTCs also misappropriated public health arguments on yields (particularly the controversy over the merits of reducing tar and nicotine levels) as a further means of undermining the directive[210].

By brand ingredient disclosure
Health advocates were supportive of brand-specific ingredient disclosure[206, 40], a TPD requirement that seriously concerned the industry (and, the documents suggest, particularly PM)[208, 71, 209]. PM drew up message points on behalf of CECCM for use in lobbying on ingredient disclosure[211]. These suggested it was willing to disclose ingredients, but not “specific recipes” (i.e. detailed individual brand ingredients), arguing that this would be consistent with rules on other consumer products such as food[211]. To this effect PM developed a series of alternative disclosure models. Those which were brand-based gave only percentages or quantity not exceeded by groups of ingredients, with flavourings considered as a single item[212-214]. Other so-called composite lists did quantify individual ingredients, including flavourings, used by the manufacturer but did so across all brands rather than on an individual brand basis[215]. Importantly, the various models proposed never disclosed non-tobacco ingredients by brand and weight[216]. At one point PM enjoyed some success in inserting one of its preferred models for ingredients disclosure into the TPD text[217] although this amendment was later overturned (see Table 5)[218].

Graham Smith (BAT Manager of Regulatory Issues), charged with developing arguments on ingredients and testing, claimed there was no scientific reason for ingredient disclosure, stating:

“much of what is proposed is politically, rather than scientifically, driven”[129].

Like PM, he recommended that BAT indicate that it was prepared to provide data similar to that required of the food industry, supplemented, if necessary, by an industry or company (rather than brand based) list of ingredients[129], the over-arching aim being to avoid the disclosure of proprietary information.

Toxicological data
Although public health groups were in favour of toxicological testing and regulation of additives[206, 40], frameworks for achieving this were poorly developed. Combined with insufficient expertise, acknowledged by the Commission (interviews with Commission officials, August and September 2008, and health lobbyist, August 2006), this enabled the industry to seize the initiative[76], getting Commission staff to agree to establish technical groups with industry representation to work with the Commission on this and related issues[219-220], as detailed further below (Section 4.4.1).
BAT developed several arguments to undermine this aspect of the directive, claiming it placed an “impossible burden on manufacturers that might lead to the removal of all additives”, that it failed to define clearly which constituents required testing, or which methods were acceptable for demonstration of safety[221, 208, 129]. Responding to a health lobby publication[206], the industry also refuted claims about the role of additives and cigarette design in enhancing addictiveness[222]. It was most vocal in its defence of the use of ammonium compounds[223-224], which evidence shows the industry has used to enhance the addictiveness of cigarettes[25-27]. Confusion about additives was reflected in the directive’s passage; a clause banning ammonia that had been inserted by Parliament at its first meeting was later deleted on the Commission’s recommendation[225] (see Table 5).

**Derogation**
Once the product content and labelling provisions appeared settled, BAT appealed for a longer transition period[226-230]. The 1999 Commission proposal envisaged that the directive would come into force on 31 December 2001 with a two year period of transition during which non-compliant products, including higher yield products, could be marketed. A temporary derogation for Greece for tar yields until Dec 31 2006 was also anticipated[45]. From the industry’s perspective some success was achieved in prolonging the transition period at various points in the negotiations although this was largely because it was one of the issues on which the Commission, Parliament and Council failed to agree during the initial readings (see Table 5). During the conciliation procedure, therefore, a compromise was reached; the final text included a derogation for application of yields until 31 December 2006 for products manufactured in the EU but sold outside. For other aspects of the directive, it was agreed that non compliant products could be marketed for up to one year, and non-cigarette products for up to two years after the directive came into force[10](See Table 5).

**4.4 Industry lobbying tactics**

**4.4.1 An overview of industry lobbying**
Ultimately, success or failure for the industry was dependent on its lobbying machinery. The TTCs had long scrutinised the developing EU legislative process and by the mid-1990s had a well established lobbying network and strategy in place, which had been developed following advice from a number of sources[231]. Advice obtained by PM, for example, on improving its influence in Brussels had identified the need to be seen as a “solid EC citizen” and outlined key points of influence, describing the Commissioner and his Cabinet (personal office) as “the “silver bullet” sort of immediate influence” and the CoM as a “crucial target”[232]. Later advice, in relation to a separate tobacco control issue, had outlined how best to exert influence in the CoM[233].
A CECCM discussion paper produced in October 1999, shortly before the formal TPD proposal was published, outlined a lobbying programme designed “to succeed in influencing the EU decision making process”[67]. This provides insight into both CECCM’s general lobbying strategy in Europe and its approach to the TPD. The strategy prioritised the creation of a “solid contact network” with “speaking partners” in the key EU institutions: the Commission, EP and CoM, as well as EESC and CoR[67]. The plan aimed to ensure CECCM was regarded as a “credible counterpart in any discussion on tobacco related issues”[67]. Following the resignation of the previous Commission as a result of allegations of corruption[234], special mention was made of identifying contacts in each of the relevant, new cabinets of the Commission, not just within DG SANCO, but also the departments of Internal Market and Industrial Affairs, Taxation, and Agriculture[67]. The new Parliament similarly offered opportunities to build a “privileged relation[ship]” with selected MEPs through activities such as writing letters of congratulations and hosting social events to coincide with key committee meetings. In relation to the TPD, CECCM noted that a dialogue with the responsible rapporteur would be key. The CoM’s Secretariat was also identified as a precious source of information and one which might influence the process and “elaboration of the common positions”[67]. In member states CECCM noted the need for NMAs to play a key lobbying role particularly in countries holding the six-monthly rotating EU presidency during the development of the TPD[67].

Key BAT and JTI documents outline specific strategies for influencing the TPD, targeted according to the stage of the directive’s progress through the co-decision process[66, 137, 142, 69] and the country holding the EU presidency at each stage, and were updated as the directive progressed[68](see Table 5). As indicated above, these strategies varied somewhat across companies. BAT aimed to “delay” the directive’s progress by awaiting the ECJ judgement (as well as by delaying the date of implementation as described above), to “amend” the directive by removing the export requirements in articles 3 and 7, and ideally to “block” the directive’s passage altogether[137, 80, 77, 235]. Although the export issue remained a top priority throughout the TPD’s progress, BAT also focused on other provisions of the directive, such as misleading descriptors and ingredients disclosure[68]. JTI’s focus was similar, but by September 2000 it was already planning legal challenges based on Community competence and WTO violations[69]. PM’s more modest objectives were focused on engaging in consultation with the Commission, acting alongside CECCM on ingredients disclosure, measurement methods and toxicology testing[220, 219, 236].

A BAT document outlining a national action plan for Germany illustrates how the argumentation discussed in the previous section could be transformed into “messages” for delivery by “messengers” (e.g. national companies or manufacturing associations) to key “targets” (e.g.
ministries, national and European politicians and the media)[99]. It also illustrates how the lobbying tactics could be usefully sub-divided into direct tactics (those targeted at organisations/individuals with direct influence on policy) and indirect tactics (working via third parties acting on the industry’s behalf) (see Figure 1).

**Figure 1: Industry lobbying targets**

4.4.2 Indirect lobbying

*Enlisting tobacco allies*

Various stakeholders were identified, including employees, unions, farmers, suppliers, distributors and, of course, the media, with plans being made to enlist their support in key countries[235] using carefully targeted messages[99]. Farmers and suppliers, for example, were to be told that the directive would force EU companies to move production outside the EU, making it likely that manufacturers would source their leaf and other supplies from non-EU producers[99]. The unions, who were to be told that manufacturers were being “forced” to consider relocating production[99], played a key role in lobbying, particularly in presenting economic arguments, generating press interest and enlisting political support[237, 183]. The UK Tobacco Workers Alliance (TWA), a cooperative of several trade unions**, was described as “unrelenting in their [sic] efforts” to lobby against the directive[237, 162, 238], and, along with other unions, played a role in organising protests against the directive. The Transport and General Workers Union and Britain’s General

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*cc Including the Manufacturing, Science and Finance Union (MSF) and the Amalgamated Engineering and Electrical Union.*
Union also played a role. Tobacco workers and trade unionists from the UK were transported to Brussels at the time of key Council meetings in order to promote their concerns. At an EU level the industry managed to obtain support from the European Committee of Food, Catering and Allied Workers Unions, which issued a press release highlighting the “massive negative social effects on employees in the tobacco sector”.

Media coverage
Public relations formed a key component of the industry’s strategy and plans to use the media at local, national and European levels, with a focus on employment aspects, were successfully implemented. In the UK, press releases highlighted (and local and national media coverage subsequently focused on) the alleged job losses associated with the TPD, rather than any potential health gains. This focus, along with union lobbying efforts, appeared invaluable in securing broad national and international coverage on the industry’s behalf although BAT also resorted to placing its own articles, advertisements and letters within the media to generate further coverage.
### Table 5: Key stages in industry lobbying

<table>
<thead>
<tr>
<th>Stage*</th>
<th>Events (for more details see table 2)</th>
<th>Industry activity</th>
<th>Voting outcomes &amp; key amendments to text</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st stage</td>
<td>DG SANCO announces intent to legislate and consults on proposals</td>
<td>Develop argumentation against further harmonisation sending written submission to DG SANCO to this effect; establish technical groups to develop detailed arguments against key provisions.</td>
<td>Commission fail to respond to industry arguments and do not amend the directive.</td>
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<tr>
<td>Nov 1998-Nov 15th 1999</td>
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<tr>
<td>2nd stage</td>
<td>Directive adopted submitted to EP &amp; Council</td>
<td>Meetings between various pan-industry groups (eg CECCM, GITES, and ESTA) and Commission, including technical meetings established at industry’s request.</td>
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<tr>
<td>Nov 16th 1999-Jan 2000</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>3rd stage</td>
<td>EP committee stage (opinions from Legal Affairs, Industry and Environment Committees in Parliament, and from EESC and CoR)</td>
<td>Carefully scrutinise EP committee member interests and voting patterns. Lobby MEPs, particularly Committee members and rapporteurs, to highlight flaws in legal base and appeal for changes to the text. Use VdC contacts, German MEPs Langen and Lechner (rapporteurs of the Industry &amp; Legal Affairs Committees respectively) to push for legal review, and, with other MEPs, to table amendments including deletion of export requirements, reduction in health warning size and removal of ban on misleading descriptors[249, 66].</td>
<td>May 2000: Industry and Legal Affairs Committees, with industry friendly rapporteurs, deliver negative opinions on the directive. At 1st Reading EP adopts 44 amendments with overwhelming majority. Most are critical of industry including insertion of ban on ammonia (and other addictive additives) and increase in health warning size[250, 217]. Ingredients disclosure model proposed by PM voted in[217] but other industry supported amendments, including removal of export restrictions and allowance of descriptors authorised by Member States, did not find favour[251]. EP amendments noted by industry to be more radical than Commission’s[81].</td>
</tr>
<tr>
<td>Jan-Jun 2000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4th stage</td>
<td>From EP 1st reading to Council agreeing common position</td>
<td>Action at member state level and in Brussels to make the case on the legal base and to amend the directive[77]. Focus on potential abstainers, identified as UK, Greece, Denmark[252, 66].</td>
<td>Commission responds positively to EP amendments, accepting most, rejecting others and making additional amendments including a longer transition period. At Health Council meeting Germany votes against; Spain, Luxembourg, Austria abstain[252, 66]. Council adopts 17 of the EP’s amendments (some of which the Commission had rejected); rejects 21 other EP amendments; and introduces 3 new minor changes. Rejects EP proposals for increase in health warning size and ban on ammonia, the latter attributed by BAT to “careful management of the debate on additives”[81]. However also rejects PM’s model of ingredients disclosure (inserted by the EP) and longer transition period for yields.</td>
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<tr>
<td>end June to end July 2000</td>
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<tr>
<td>5th stage</td>
<td>From common position to EP second</td>
<td>Employ “three level defence strategy” to delay, amend and block the directive[253, 77, 235]. Within the EP the key aims are to</td>
<td>Common Position considered by Commission as less ambitious than EP proposals. Numerous amendments proposed in</td>
</tr>
<tr>
<td>Aug-Dec 2000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage</td>
<td>Event</td>
<td>Details</td>
<td></td>
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<tr>
<td>-------</td>
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<tr>
<td>6th stage, Jan-May 2001</td>
<td>Commission and Council’s Opinion on 2nd reading leading to Conciliation process and final, third reading.</td>
<td>Working towards getting blocking minority in CoM by building stakeholder support &amp; influencing ministries in “target” countries (Spain, Austria and Luxembourg who voted against at 1st reading) and “potentials” (Denmark, Greece and UK). Worked through NMAs; targeted non-health ministries (using economic impact arguments) involved unions and other stakeholders eg farmers. Write to Conciliation delegation, UK government and Commissioner Byrne. BAT taskforce views conciliation as extra time to address manufacture in transitional period and “…safeguard the things we have achieved, such as the trade marks derogation for descriptors and the derogation amendment for export”.</td>
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<td></td>
<td>Commission’s opinion on 2nd Reading: accepts 22 amendments; but cannot accept others including exception for registered trademarks from descriptor ban, longer transition periods, ban on ammonia and additives (citing for the latter, insufficient evidence). Council also unable to approve all Parliament’s amendments and conciliation process begins.</td>
<td>Compromise text ultimately approved by Council and EP at 3rd reading in May 2001. Amendments approved include: compromise on size of health warning labels; all misleading descriptors, including trademarks, prohibited; delay in application of yields for products manufactured in EU but sold outside to 31 December 2006; longer transition period for marketing of non-compliant products.</td>
<td></td>
</tr>
</tbody>
</table>

* Stages 1-4 outlined by BAT document[66]. Stages 5-6 added by authors.
4.4.3 Direct Lobbying

4.4.3.1 The Commission

The Commission was the key lobbying target early in the directive’s development (Table 5)[66]. A tripartite meeting in July 1998 to discuss the proposed directive brought together representatives from DG SANCO, health organisations and the industry[260]. CECCM’s view of the meeting was that the health representatives did not believe the industry and challenged their integrity[95]. After the event, Paul Sadler of BAT, wrote to Dr Hunter (Director of DG SANCO) to express his disappointment in the meeting and his belief that tobacco company views were not appreciated[261].

Poor relations with DG SANCO appeared to continue once David Byrne took up post as Health Commissioner[262, 127]. In meetings between Byrne, his staff and tobacco industry representatives in October 1999, during the period of inter-service consultation, it was made clear to the industry that it was held in very poor regard and would have to work to earn the Commission’s trust[262, 127]. Byrne emphasised that he was sceptical of the industry’s intention to reform, despite PM’s claims to this effect[127]. CECCM therefore felt that active lobbying of the Commission before the directive’s adoption would potentially damage the consultation process and trust-building[262]. Thereafter the industry attempted to demonstrate it was “reasonable” and “solution oriented”[78] and lobbying of Commissioner Byrne appears to have been limited. Interview data confirm this and suggest it was probably because the industry knew it would neither receive a warm reception (interviews with EU legislator, August 2006 and September 2008) nor a desired outcome (interview with European Commission official, August 2008).

Thereafter, tobacco companies and their allies resorted to written correspondence with Byrne to outline their objections[131, 228, 263]. Byrne rejected the economic and employment claims made by BAT, a fact which chairman Martin Broughton claimed to find astonishing, warning Byrne in a letter that the draft directive was:

“seriously flawed…contradictory and illogical in its purpose and intent. It deserves to be challenged in the Courts. …The introduction of another bad law without full consultation and justification or any proper assessment as to its impact will bring the EU further into disrepute”[139].

When Byrne remained resolute in his response[140], Broughton mentioned the possibility of litigation in a letter of January 2001[228].
Given the poor relations with DG SANCO, the industry lobbied Commissioners in other DGs, with BAT identifying DGs Competition (Monti), Enterprise/Competitiveness (Liikanen)\textsuperscript{dd}, Internal Markets (Bolkestein), Trade (Lamy) and Employment (Diamantopoulou) as key targets later on in the TPD’s passage\textsuperscript{[235]}. This modus operandi was noted by DG SANCO officials (interviews with European Commission officials in August 2006 and August and September 2008). BAT lobbyists received some assistance from DG Employment, where an official had suggested they request a copy of minutes concerning the impact on jobs from the General Secretariat\textsuperscript{[182]}.

Although Commissioner Byrne may have been reluctant to engage with the industry, other DG SANCO officials were deemed more approachable. Lobbying of such officials occurred through two routes: general meetings between industry and DG SANCO members, and separate technical consultations on scientific and technical elements of the directive\textsuperscript{[264, 220, 219]}. The agreement to hold these technical consultations on four key topics, (yields, labelling, descriptors, and additives, measurement methods and toxicological testing), had been secured at a meeting between industry representative and DG SANCO officials on 23\textsuperscript{rd} November 1999\textsuperscript{[219-220]} and was described by the industry as “a major step forward” which would enable them to engage the Commission in detailed discussion on the directive\textsuperscript{[219]}. Industry notes of the meeting record one official showing “flexibility and a willingness to listen” concluding that his continued involvement “will be absolutely crucial”\textsuperscript{[220, 219]}.

Subsequent technical meetings in February and March 2000\textsuperscript{[207, 265-267]} fitted PM’s strategy of “dialogue” with regulators\textsuperscript{[112]}. In addition to engaging the Commission in dialogue, the industry hoped to offer its expertise on cigarette design and to persuade the Commission to make the “necessary changes” to technical provisions\textsuperscript{[268]}. Since the directive was particularly “vague” on technical issues, and Commission expertise limited, the industry flooded the Commission with information that it did not have the capacity to appraise (interview with EU legislator, August 2006 and September 2008). In essence, as the industry also noted, insufficient guidance on the format for ingredient disclosure or measuring and testing of additives assisted the TTCs to push their own models\textsuperscript{[265, 269]}.

Although some Commission officials may have outwardly welcomed industry proposals\textsuperscript{[267]}, they were then required to meet with the industry as a stakeholder and failure to do so would have prompted industry complaints to the contrary (interviews with European Commission officials in August and September 2008).\textsuperscript{ee} Commission officials did, however, see value in meeting the industry on product regulation issues, to establish meaningful technical standards, but denied these meetings had any

\textsuperscript{dd} Around the same time, Commissioner Liikanen became involved in meetings of the Fair Regulation Campaign which, as described above, BAT was a founding member of\textsuperscript{[195]}. Not only did Liikanen appear very supportive of BAT’s aim to promote a form of business impact assessment within the EU, he also oversaw a pilot study on business impact assessment to which BAT contributed, via the European Policy Centre\textsuperscript{[172]}.

\textsuperscript{ee} It is important to note that Article 5.3 now removes this obligation
direct influence on the final directive (interviews with European Commission officials in August and September 2008). This is largely consistent with industry records of events[66, 270]. BAT, for example, noted following various meetings with Commission staff and industry organisations that:

“Unfortunately no result of the argumentations presented at these meetings found its way into the directive. The Commission did not react in any way to the arguments advanced by the industry”[66]

4.4.3.2 The European Parliament (EP)

Having failed to secure changes before the directive was passed to the Parliament in January 2000, industry lobbying turned to the EP. The first reading at the EP was held from 13th to 14th June 2000[66], immediately before the Advocate General’s ruling on the Advertising Directive was delivered[3]. The committees were key to the directive’s progress and industry lobbying inevitably targeted the key committees through which the directive passed before the plenary vote[66, 271]. The industry regarded the Legal Affairs Committee, which had previously “struck down” the advertising directive, as one in which they could “score victory”[271]. Carefully scrutinising Committee members and their voting history on the advertising ban, they felt that by reiterating the lobbying efforts used on that and “questioning the choice of Article 95 for certain aspects of the proposed directive”, they might be able to gain sufficient votes against the directive[271]. As detailed above, in February 2000, Scott Crosby, a solicitor instructed by BAT, wrote twice to Professor Neil MacCormick, a MEP who served on the Committee, suggesting he would find an ally in Lord Inglewood (a fellow committee member) and appealing to him to contest the directive’s legality through the committee and “further afield if possible”[132], claiming:

“the proposal will be waved through unless someone, or some Committee cries foul….I put it to you that the Legal Affairs Committee must give clear advice to Parliament as a whole that the proposal must be rejected”[135].

And suggesting:

“if you could in some public way expose the Commission’s argument in law for what they are – a complete sham - I would be grateful and so too would my client”[132].

By early May 2000, BAT’s Stephen Waltzer and Scott Crosby had met with Ana de Palacio, a Spanish MEP and chair of the Legal Affairs Committee[134]. The following day, Crosby sent her a selective set of opinions detailing the “illegality” of the proposed directive. This did not include the opinions that had found in favour of the directive and Crosby even critiqued Vilaça’s opinion for erring in suggesting that Article 95 (3) was a legal basis. He pushed for the Committee to state that the proposed directive was unconstitutional and that legislation should await the ECJ judgement on the advertising ban[134].
The VdC had sympathetic German contacts in Kurt Lechner, rapporteur of the Legal Committee and Werner Langen, rapporteur for the Industry Committee[136, 66], who proved invaluable to the industry[66]. Lechner forwarded to his industry contacts his report for the Legal Affairs Committee on the “ultra vires” nature of the directive, before its official release[272] and jointly, having made public their reservations about the legal basis and negative economic impacts of the directive in a press release[273]. Lechner and Langen pushed for these committees to request a legal opinion from the Parliament’s legal advisor[136]. In line with industry suggestions made elsewhere[134], they also called for a moratorium pending the ECJ decision[249]. As members of a group of 39 MEPs, they tabled several amendments to the directive including a deletion of the export requirement, a smaller size and weaker specification for the health warnings, and the use of misleading descriptors in most circumstances[249], all key changes the industry desired. Described by BAT as “critical amendments”[66], these changes would have diluted the directive significantly, but were rejected in the plenary vote on June 14th 2000.

Following the Legal Affairs Committee rejection of the directive’s legal base[48] the industry focused on other committees still yet to meet, notably the Industry and Environment Committees[274]. The TMA sought support from British Conservative MEPs, contacting those who were members of these Committees and suggesting that the individual companies follow up with their own efforts[274-275]. Simultaneously, the TWA union wrote to committee members from a broader group of political parties[274]. Perhaps facilitated by Langen as rapporteur, these efforts appear to have had some impact in the Industry Committee, which was later described by BAT as “helpful” in the first reading[107].

However, industry efforts in the Environment Committee, the lead committee for the directive, were far from successful[66]. Jules Maaten a Dutch MEP was appointed rapporteur of this Committee and the Dutch Manufacturers Association and ECMA, “because of close personal relationships with Maaten”, mainly handled industry contacts with the Environment Committee[66]. This included a visit to Bergen op Zoom in the Netherlands, the largest PM factory outside the US[66]. Industry operatives claimed to be shocked when Maaten, who went on to play a crucial role in securing the success of the directive, delivered what it described as an “entirely negative report” that was critical of the industry[66].

Despite these wide ranging efforts by the industry, the Parliament strengthened the directive[81]. By the end of its first reading the EP approved a total of 44 amendments, most of which “were very critical of the industry and even more radical than the Commission’s proposals”[66]. An amendment prohibiting ammonia compounds and other addictive components was inserted, as well as provisions for larger
and more detailed health warnings, while a clause allowing exceptions to the misleading descriptors was deleted. However PM achieved a major amendment to the ingredients disclosure provisions.\footnote{This was changed from a list of all ingredients with exact quantities specified to a model promoted by PM with two composite lists of quantities not exceeded.}

Some of these amendments found favour with the Commission and then the Council, both of which then made further amendments to the directive (Table 5). In the Common Position adopted by the Council on 31st July 2000 and returned to Parliament in September that year, it was clear that the industry had failed to secure a deletion of the export restrictions, an exception for misleading descriptors, or a longer transition period. The Council had, however, rejected the ammonia ban inserted by Parliament and reduced the size of the health warnings that were to be required (see Table 5).

By the time the directive was returned to the Parliament for its second reading, in December 2000, BAT and JTI had had updated strategies and key messages\cite{19}. BAT’s key focus remained opposition to the export restrictions and it wanted the advertising ban ruling\cite{82, 107} to influence proceedings as it later did\cite{114}. JTI focused, inter alia, on the descriptors ban, the export restrictions, carbon monoxide yields and the size of the health warnings\cite{69}.

BAT’s primary focus in Parliament remained members of scrutiny committees\cite{107}. Secondary targets were the presidents, vice presidents and spokespersons for political groups, since “it is here that voting patterns are agreed”\cite{107}. Particular focus was on the EP’s largest political groups\cite{107, 235}, BAT systematically identified target MEPs, circulating lists by country and order of priority to its in-country staff for lobbying purposes, stressing that contact had to be maintained and feedback circulated in order to assess remaining priorities\cite{107}. Feedback on MEPs who appeared to be useful was gathered, including from the trade unions involved, in order to aid plans for targeting messages\cite{276}.

British Conservative MEPs had voiced their opposition to the export requirements at the first reading\cite{277} and an email reporting progress within BAT noted that their support “against the export restriction is expected to continue”\cite{182}. Conservative MEP, Roger Helmer, whose East Midland’s constituency was home to 200 Imperial tobacco workers, had undertaken to hold a public meeting on the directive in conjunction with BAT, to which Labour and Liberal MEPs would be invited, as well as to write to the UK Under-Secretary of State for Health\cite{182}. The letter focused on the export requirements, contesting their legality and describing them as “neo-colonialist”\cite{278}. Elsewhere Helmer described the directive as “pointless and damaging. It is political correctness run mad”\cite{279}. It was also noted that a Dutch Socialist MEP, Dorette Corbey, who had spoken out against the export provisions in the plenary session of 13th June was willing to table an amendment to that effect, which other MEPs would apparently support\cite{182}.
The union-based lobbying, described above (Section 4.4.2)[237, 162, 238], enjoyed some success in generating support amongst MEPs[276]. The UK economic impact study published jointly by BAT and several trade unions in September 2000[164], stimulated written questions to the Commission from MEPs, such as Glyn Ford (UK Labour Party), on whether the Commission itself had carried out a comprehensive assessment[182]. Following briefings, he made a speech strongly arguing the TWA case in Strasbourg[237]. Ford and Stephen Hughes MEP (another UK Labour MEP), were described by BAT as “exceptions” in the Labour camp[280].

The documents indicate that the industry secured the support of German Conservative MEPs, Werner Langen (who as described above had already been liaising with the industry), Karl-Heinz Florenz and Peter Liese in tabling amendments to the directive in the Environment committee[281-282, 254]. Rolf Bielefeldt of BAT revealed that he knew both the wording of the amendments to be proposed by these German MEPs and which MEPs would introduce them in advance of the meeting on 16th October, referring to a “current agreement with these members” and noting the sensitive nature of the document [282]. The amendments tabled by the three Conservatives aimed to delete the export provision from Article 3 (maximum yields) of the directive[282-283, 281] and were tabled as planned[254]. Other amendments were tabled in the Environment Committee by various other MEPs including a Greek MEP, a German and Dutch Socialist MEPs, and a British Conservative MEP[254], that the documents suggest the industry may have had links to[283, 282, 182]. These amendments included a delay in the application of the export provisions, that BAT later claimed to have achieved[258].

In light of the ECJ ruling on the advertising directive and the position being taken by the Council, Maaten (amongst others) proposed a series of amendments for consideration by the Environment Committee meeting on 21st November 2000[284, 254]. These included compromise amendments on ingredients disclosure, an exception for genuine trademarks within the descriptors ban and smaller health warnings than the EP previously recommended (albeit larger than the Council recommendations)[255](see Table 5). These changes, designed to ensure the directive’s progress, were weaker than positions taken at the EP’s first reading, and thus happened to be acceptable to the industry[114]. All were approved by the Environment Committee[255] as was an agreement to insert Article 133 and Article 152 in the Recital (to legitimise the export provisions). The industry tabled amendments, by contrast, failed to find support[255].

On 17th November, just prior to the Environment Committee meeting, Martin Broughton (BAT Chairman) wrote to Caroline Jackson (UK Conservative MEP and President of the Environment

[54] Ford represented the South West of England, home to BAT’s Southampton factory, and was also a member of the MSF, the union for skilled and professional people.
Committee), detailing the claimed threat to UK jobs and asking her “to consider this as you preside over the voting in the Environment Committee”[285]. Broughton copied to Jackson a letter he had sent Byrne[131] which, in addition to detailing the alleged employment impacts, claimed the directive was legally flawed. Jackson had previously been identified as a possible industry ally by virtue of her voting record on tobacco issues, which in fact may have had little to do with her supporting the TTC’s cause, but was rather an example of taking a stance against what she considered as non-adherence to due process and legal competency in the EU institutions[286-292].

In addition to BAT’s apparently concerted efforts, CECCM remained active, coordinating positions amongst its members[293]. Despite these efforts, the industry largely failed to secure all the changes it desired. The industry-backed amendments were not adopted at the second reading, whilst the Environment Committee proposals, including the addition of Articles 133 and 152 and the reinsertion of the ammonia ban, were adopted[50].

4.4.3.3 Council of Ministers and COREPER
A key BAT objective was to obtain a blocking minority in the Council[235]. Germany was registered as firmly against the directive and BAT hoped that other countries might be persuaded to join it, thus establishing a blocking minority. These countries were divided into “targets” (Spain, Austria and Luxembourg, all of whom abstained in the first Council vote) and “potentials” (Denmark, Greece and UK, who had until then voted in favour of the directive)[235]. It calculated that if the “target” countries, Spain (8 votes), Austria (4 votes) and Luxembourg (2 votes) joined with Germany (10 votes), only one of the “potential” countries would be needed to secure the 26 votes needed to block the TPD[80, 107].

Building blocking minorities in the Council required influencing national governments. Both BAT and CECCM recognised that contact with national governments was best achieved through the NMA’s or a national tobacco company[67, 235]. To this end BAT sought to persuade national companies of the need enlist their government’s support against the directive by framing arguments specific to each company[235, 142]. Moreover, aware of the difficulty in gaining support from health ministries, BAT planned to concentrate on other ministries “who should be more concerned about the effect on employment and the economy”[77], hoping to mobilise them to influence health ministers[235]. A letter to economics, trade or employment ministers was drafted to this effect for use across Europe[165]. In addition, stakeholders, such as employees’ unions and farmers in each of the “target” and “potential” counties were to be contacted for support[235].

\[hh\] For example in Austria, Austria Tabak was to be persuaded of the need to protect its brand Milde Sorte (threatened by the ban on descriptors), Papastratos in Greece, House of Prince in Denmark and Heintz van Landewyck in Luxembourg were to be convinced of the “threat to exports”, and Altadis (Spain) of the need to protect air-cured tobacco and export production[235].
Most detailed documentary evidence of how governments were lobbied centres on the UK and Germany. Whilst this reflects the importance of these countries in terms of voting[235] and the structure of the companies, it may also be related to the nature of the document collections, as outlined in section 4.1 above[58-59].

UK

BAT saw the UK government as key to its success, since the UK had a large number of Council votes[235], and occupied a dual role as ‘host country’ for the company and a key player within the EU:

“The UK government should be a champion for BAT….supporting …and promoting exports, helping open new markets (state monopoly countries), promoting intellectual property protection…UK is a reference point and pioneer in regulatory and health debates and punches above its weight in EU and international circles”[294].

BAT, at that time developing a formal corporate social responsibility strategy driven in large part by its loss of political authority[295], was aware that its image in the UK had been tarnished by allegations of cigarette smuggling investigated by the Health Select Committee between 1999 and 2000[294, 296]. Nonetheless, industry representatives lobbied the Labour government, concentrating on UK ministries with relevant portfolios, notably the Department of Health and DTI[154, 297].

The Department of Health had, under the new Labour government, welcomed the proposed directive, and communicated its support to all UK MEPs[298]. Despite meeting with and writing to the Department’s Tobacco Policy Unit regarding the proposed directive on a number of occasions, BAT failed to obtain the response it had hoped for[299, 186, 197-198, 187]. Once BAT and the TMA conceded that the Department of Health was resolute in its support of the directive, BAT’s Chairman and Director of Corporate and Regulatory Affairs sent letters voicing their concerns to the Secretary of State for Health, Alan Milburn[163, 300] and the Permanent Secretary, Chris Kelly[130]. In line with BAT’s efforts to re-position itself as a responsible company[235], these letters stressed that BAT was in favour of sensible regulation[163], but claimed the directive was “far from sensible”[163], highlighting concerns about the directive’s legality, impacts on jobs and ability to achieve health benefits[163, 300, 130]. Despite their rather threatening tone (See Box 2) these letters failed to deliver a favourable response[301].
Box 2: Excerpts of a letter from Martin Broughton (BAT Chairman) to Alan Milburn, UK Secretary of State for Health[300]

I fear it is my duty to make it clear that redundancies and factory closures are inevitable if the draft directive is adopted in its present form. We will have no choice but to move production out of the UK……..

There seems no reasonable explanation as to why the Government will not consider the anti-competitive and unlawful nature of this export ban, which cannot deliver health benefits outside the EU. It is not too late for the UK to reconsider its position and to save thousands of jobs.

As you know I have serious reservations about many other aspects of this proposal, not least its legal base, but now is the time for clarity. If you do not act now, UK cigarette factories will close, as will supplier companies.

Surely the lesson that the tobacco advertising directive has taught us all is that badly drafted legislation with a questionable legal base at best serves only to bring the whole EU process into disrepute. …

Urgent action is required. Thousands of people are looking to the UK Government to ensure that their jobs will not be lost in a futile sacrificial gesture. You will be aware that the European Parliament and Health Ministers are already involved in a Conciliation Process which will seek to finalise this health measure, which is improperly proposed as a single market and trade measure.

I hope you will be able to give this your immediate attention.

Industry efforts directed at the DTI initially showed greater promise when, in Spring 2000, during a meeting with DTI officials, it was suggested that letters from tobacco company Chief Executives to the Secretary of State, Stephen Byers "would carry a good deal of weight"[297]. The official responsible for tobacco at the DTI, Julian Ebsworth, was described in a memo from BAT lawyer Stephen Walzer as "sympathetic" to the industry's concerns[154]. Walzer’s memo is indicative of the disingenuous nature of some industry argumentation:

"it would be nice if Martin [Broughton, Chairman of, BAT] could write a letter to Byers [Secretary of State at the DTI] asserting that production would move outside the [European] community and that [BAT’s factory in] Southampton could be at risk. I then ask myself the question ‘is this true?’……now would be an excellent time to play on DTI nerves, dressing up those nerves by using the trade card, i.e. illegality as far as the WTO is concerned"[154].

Having heard that the Trade Policy Directorate’s WTO unit in the DTI was liaising with the Cabinet Office on the matter, the TMA sent copies of its submissions to the Department of Health to the DTI[297]. Rumours had circulated that DTI thinking was influenced by the recent BMW/Rover “debacle”ii resulting in a growing concern to avoid closure of more UK manufacturing bases[297]. Martin Broughton did secure a meeting with Byers in May 2000[302], despite initial reluctance by the

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ii The DTI intervened in 1999 with a large aid package in an effort save the struggling Rover Group’s car manufacturing plant near Birmingham, an investment which was criticised heavily by the media and EC competition officials alike.
Secretary of State. The meeting only took place following pressure from the Prime Minister’s office after Broughton had enjoyed a breakfast meeting with Prime Minister Tony Blair by virtue of Broughton’s membership of a privileged lobbyists group of multinational company chairmen[303]. However, subsequent industry correspondence[304, 302], did not sway DTI’s commitment to the directive[305-306]. A meeting was convened in October 2000 between Patricia Hewitt of the DTI and Yvette Cooper of the Department of Health, along with Members of Parliament (MPs) with factories in their constituencies, the TMA and trade union representatives but the outcome was described by the TMA as “disappointing”[307, 162]. Furthermore, BAT and the TMA later discovered that any DTI scrutiny reserve on the directive had been lifted, indicating that DTI had transferred full negotiating authority to the Department of Health at COREPER meetings[308].

Efforts were also made to secure support via UK MPs as well as UK MEPs. These politicians were targeted via a letter-writing campaign[309] and through various receptions, dinners and party conferences[162, 183], and via visits to the House of Commons[241, 162, 310]. Conservative MPs were considered more open to influence[183], although some Labour MPs with tobacco manufacturing bases in their constituencies were also supportive, one tabling a Commons motion urging the government to drop its support for the directive[162, 310] and facilitating a TWA mass lobby of Parliament[162]. Two Southampton MPs, were noted to be supportive on employment issues[237, 183], although one was keen not to be publicly associated with the industry’s campaign, insisting that he argue its case with Ministers behind the scene[237]. In contrast, the TMA reported that Alan Milburn, the Health Minister, incensed the unions by his “obdurate, arrogant manner” and his desire to see his local factory in Darlington, which he considered an embarrassment, closed[237, 162].

**Germany**

By contrast Germany lent a predictably sympathetic ear to the industry, which was consistent with its previous roles in opposing EU tobacco control measures, including leading the legal assault against the Advertising Directive[4, 311, 231]. The German Permanent Representative passed on DG SANCO’s analysis of existing additives regulation in European member states to VdC in 1998 before it was officially published[312]. A year later, Axel Heim of the VdC reported to a German pan-industry lobby group in October 1999 that:

> “Chancellor Schröder’s office intends taking action to ensure that the draft directive is moderate and balanced”[313].

Germany was the only country to vote consistently against the directive in the CoM, and VdC documents suggest that the industry-supportive positions taken by Germany in the Health Council working groups followed closely from suggestions made by the industry. In December 1999, VdC members, Wolfgang Oberrecht and Axel Heim, wrote to five German Ministries plus the Chancellery,
the Foreign Office and the German Permanent Representative in Brussels, outlining the VdC’s objections to the directive and requesting that the German delegation raise scientific and legal concerns on its behalf[314]. Following further VdC-government meetings and correspondence[315-317] the German government resolved to push for key measures or interventions suggested by the industry, including a legal review by the Legal Service of the Commission or the Council, a detailed impact assessment, changes to certain definitions within the directive (including the carbon monoxide to tar yields ratio, removal of the export prohibition, a specification of a “sender” on health warning labels and a single health warning stating that “tobacco may be lethal”); and to ensure further negotiations along these lines[318]. The extent of VdC influence on the German government is suggested by a note to CECCM on 18th January 2000 by VdC member Reinhard Pauling, in which he mentions that the Chancellery and Seibt, a staff member of the Federal Ministry of Economy, who had participated in the Health Working Group meeting on 12th January 2000, wanted to consult the industry further before fixing their position[319][translated from German].

COREPER
Successive attempts were made to influence the Permanent Representatives. For example, BAT asked Guy Dutreix of Altadis (formed during 1999 by the merger of French SEITA with Spanish Tabacalera), to submit new wording on misleading descriptors enabling their use if part of a registered trademark, to Philippe Etienne, the French Permanent Representative, when France held the EU Presidency[320]. BAT simultaneously petitioned the Permanent Representatives of Sweden, Portugal, The Netherlands and France on the “technical problem” of manufacturing non-compliant products during the transition period[227]. It is not clear whether the permanent representatives followed the industry’s lead but none of the amendments requested appeared in subsequent texts or in the final directive.

4.5 Legal action
The industry was well-versed in litigation against the EC and Member States and, following the annulment of the Advertising Directive, threatening legal action was thus a powerful weapon and also an excellent stalling mechanism.

In 2000, before the directive had passed into law, BAT filed an access case to the Court of First Instance, requesting access to the international scientific research the Commission had considered and based its proposals on[321]. Since such documents were limited to recommendations from the 1996 Helsinki Consensus Conference on Tobacco[322], this case was dismissed by the European Court of First Instance, which upheld the Commission’s argument that it could not accede to an access request when the documents requested did not exist[323].
By September 2000, JTI was exploring options for litigation. It acknowledged that only a Member State could initiate an ECJ challenge based on Article 95 against the draft directive, and that it might be difficult to induce a Member State to do so, particularly since it appeared that their principal ally, the German government, might no longer be willing to act alone[78]. The alternative option was a post-implementation challenge through the national courts, in the hope that the national courts would then refer the matter to the ECJ[78]. The complexities of achieving this, given the lack of industry unity and PM’s opposition to using legal arguments, were outlined[78].

Nevertheless, within a few months of the directive passing into EU law, BAT, Imperial and JTI, initiated legal proceedings in the British Courts, which were subsequently, as the industry had hoped, referred to the ECJ for a ruling. The tobacco companies argued that Article 95 was inadequate as the legal basis of the directive, claiming it was a public health measure being introduced as an internal market measure. The plaintiffs also argued that the introduction of Article 133 as a supplementary legal basis invalidated the directive, since Article 95 and Article 133 followed incompatible legislative processes, and that the principles of proportionality and subsidiarity had been infringed. The plaintiffs further maintained that the labelling provisions for yields and larger health warnings (Article 5 of the directive) and the ban on misleading text (Article 7 of the directive) breached trade mark and intellectual property rights (Article 925 EC, the fundamental right to property and/or Article 20 of the WTO Agreement on TRIPS) and infringed Article 253, the duty to give the reasons on which directives are based. JTI made a specific submission under this banner to protect the use of its ‘Mild Seven’ trademark for cigarettes. In 2002, the ECJ declared the directive valid[321]. However the Court did rule that descriptors such as “lights” and “mild” could be permitted on cigarettes manufactured for export[321]. In its judgement, the Court explained that the Article 7 text on descriptors did not make explicit a manufacturing restriction, unlike that laid out for maximum yields in Article 3. This would suggest that it was simply an oversight in draughtsmanship, perhaps as a result of the challenges of incorporating numerous amendments, which tipped the Court’s opinion towards the industry’s argument.[ii] BAT described this as a “landmark ruling” but voiced concern that “the hand of the Commission has been significantly strengthened in relation to the member states” [324].

Two other legal challenges were launched in Member States. The first occurred in Sweden when PM unsuccessfully challenged the Swedish interpretation of the directive that the black border should be additional to the warning[325]. The second in the Netherlands in 2003, when seven tobacco companies including BAT, PM, JTI and Imperial filed separate challenges against the Dutch government’s

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[ii] When asked in interviews, Commission officials and lobbyists who followed the development of the TPD were unable to confirm whether this was an accidental omission, a trade-off or deliberate deletion following vote outcomes, but did confirm that export provisions were intended to apply to descriptors (interviews with Commission officials in August 2006 and August and September 2008 and lobbyist in August 2006).
ingredient disclosure regulations[326]. These were a strict transposition into national law of the directive whereby tobacco companies were required to submit for publication a list of ingredients and their quantities, by brand. The tobacco companies declared that such recipes were tantamount to trade secrets and that competitors and counterfeiters would profit from them if disclosed. In its judgement in 2005, the District Court of the Hague acknowledged this claim but ruled that trade secrets did not themselves enjoy absolute protection and so the challenges were rejected[327]. Imperial Tobacco and others lodged an appeal in March 2006 but this has not yet reached the Dutch courts. Since the appeal was launched, changes have been made to the national regulations, following clearer guidance on ingredient reporting provided by the Commission in 2005 and it is thought this may resolve the dispute (personal communication with Dutch health lobbyist between August and September 2008).

Further challenges concerned the directive’s ban on the marketing of certain types of oral tobacco, namely snus, first introduced in the 1992 directive and maintained in the 2001 TPD, with an exception for Sweden where snus is widely used. The challenges were brought by Swedish Match, a manufacturer of snus, along with a German wholesaler, against the UK and German governments. They again challenged the directive on Article 95, 133 and 253, but also alleged a new infringement of Article 28; the latter prohibiting quantitative restrictions in trade between Member States[328]. However, all these complaints were rejected by the ECJ in 2004 and the validity of the directive upheld[329-330].

5 DISCUSSION

5.1 Summary of findings and links to previous evidence

The TPD entered into Community law in 2001, surviving litigation with minor amendments. It had been subject to sustained attack from the tobacco industry from its initial development and throughout its passage. Preliminary attempts to persuade officials to abandon the directive as unnecessary and legally unsound failed. Once the directive moved forward, efforts by tobacco companies (particularly BAT) focused on blocking the directive and/or substantially amending its content in both the CoM and Parliament. Failing to achieve either of these, attempts were made to delay its passage and introduction. Such efforts intensified as the directive progressed.

*Articles threatening the tobacco industry*

The scale and manner of the industry’s response demonstrated that some aspects of the directive caused particular apprehension. The ban on misleading descriptors, brand-based ingredients disclosure and large health warnings were all perceived as significant threats by all companies. In
addition, the export provisions were of particular concern to those companies with significant European bases that manufactured for export (meaning all companies other than PM). The industry was not only concerned about the implications of this directive for Europe, but about its potential international ramifications. Its efforts to counter the directive should therefore be seen as part of broader attempts to obstruct the development and spread of effective international tobacco control policies. For example, the industry realised that if the EU, the world’s largest trading block, had larger health warnings, this would impact on other countries both individually and through the FCTC process, epitomised by BAT’s conclusion that “you cannot afford to ignore the EU, no matter where you are based”[331]. Similarly, efforts to influence the ingredients disclosure requirements of the TPD were linked to attempts to undermine related and more far-reaching Canadian regulation which, in setting the standards even higher, would risk further transfer of such policies.

**Argumentation**

Central to the industry’s lobbying campaign was the development of powerful argumentation against the directive carefully designed to appeal to and target various audiences from politicians to factory workers. The development of trade and economic arguments, for example, enabled the industry both to shift the agenda away from health onto other issues, where it still retained some credibility, and to engage more powerful ministries and officials in its efforts to influence the policy process.

A distinctive feature of the industry’s efforts to counter the TPD was its apparent willingness to use argumentation it knew to be contested. Thus, despite receiving initial legal opinions that the directive was legally sound (a position supported by the subsequent ECJ ruling), the industry and its representatives consistently argued aggressively to the contrary, describing its legal base as “a complete sham”[132] or “seriously flawed” and threatening the Commission that it would bring the EU into “disrepute”[139]. The industry similarly used questionable trade-based arguments against the directive, claiming that it would violate various WTO agreements, even where the substance of such threats was highly questionable. In so doing, the industry recognised the strategic value of the ‘chilling effect’ of such trade arguments[332] - the fear of litigation or trade disputes that can drive nervous policymakers towards inertia. Such tactics are not new. For example spurious trade based arguments were used in Thailand to undermine ingredient disclosure provisions[33], and in Canada to prevent the introduction of plain packaging requirements[148]. Analysis of internal industry documents relating to the latter indicates that, despite privately concluding that that there were no legitimate grounds under international trade law to block plain packaging, the tobacco companies continued to advance such arguments[333, 148].

Economic arguments against the TPD were also used aggressively, despite being dubious at best. Thus BAT produced job figures that were clearly exaggerated when compared even with other tobacco
industry sources, and publicly attributed job losses and factory closures to the TPD despite scepticism within the company - there was already a downward trend in employment in the tobacco industry and BAT was simultaneously engaged in making efficiency savings through factory closures. Again, the use of spurious economic arguments is an established industry tactic that has perhaps been most widely used against smoke-free legislation, but effectively discredited by independent evaluations of impacts on sales and employment[333-334].

Given such precedents, it is highly likely that similar arguments will be developed and used against new policy developments, regardless of their veracity. Currently this seems most directly applicable to the issue of plain packaging, which is being actively considered in at least one EU member state[39], and to which the industry has already responded aggressively[335-337], recycling arguments developed in opposition to the TPD. BAT for example, has claimed that the UK government’s ability to introduce plain packaging is “constrained by law, not only by the general principles of public law, …. and EU law, but also by international law, including the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)”[335].

A number of further issues are worth highlighting in relation to the industry’s argumentation against the TPD. First, the economic arguments, notably the threat of job losses, proved effective in garnering political support for the industry’s case, most crucially among left-wing politicians, not natural industry allies, and in engendering media interest, where coverage appears to have been dominated by the industry’s economic arguments. It is also ironic that a company that actively orchestrated job losses in tobacco manufacturing over this period was so easily able to recruit trade unions to its cause. Collectively these findings suggest that the tobacco industry was more easily able to frame debates on the economic impacts of the directive than the public health community, notwithstanding the World Bank report which was published around the same time and which highlights the cost-effectiveness of tobacco control measures[338].

Second, and closely related to this, the industry’s attempt to use economic impact studies to frame its economic arguments against the directive is consistent with evidence that, contemporaneously with its efforts to influence the TPD, BAT successfully pushed for favourable forms of impact assessment to be made an obligatory part of the EU policy process[172]. It is also in line with evidence that impact assessment can privilege industries by systematising their informational advantage[339] and again demonstrates that the tobacco industry cannot be relied on to provide accurate data on the potential economic impacts of legislation such as employment.

Third, the legal base of the directive as an internal market measure was the cornerstone of industry argumentation against the directive. This was seen as important not only for the TPD but for all tobacco
control issues in Europe and described as the “core EU battleground for the future of our industry”[117]. Given that the tobacco industry and its allies, including the German government, have repeatedly used litigation to undermine key EU tobacco measures[231, 15], it is likely that this will remain central to future industry efforts to undermine EU tobacco control policy unless the EU Treaty is revised to provide a clear legal base for binding public health measureskk. Yet it is also important to acknowledge that ECJ rulings on the advertising and tobacco products directives have established significant scope for the enactment of public health policies under Article 95.

Fourth, the TPD illustrates the difficulties encountered by officials in undertaking the highly complex and controversial task of regulating tobacco products. In this context, the Commission’s lack of expertise (see below), combined with the lack of consensus amongst health experts on the issues of tar and nicotine reduction and testing methods may have inadvertently enhanced the industry’s ability to use scientific and technical arguments against the legislation. The common ground seemingly occupied by health and tobacco lobbyists may have contributed to the dilution of Article 4 (whereby Member States “may” - i.e. at their discretion - request tobacco companies to test the yield and assess the health effects of other substances) and to compromise text in Article 13, giving Member States the option to prohibit ingredients which increase addictiveness. The consequences of such non-prescriptive text in the directive are twofold. First, Member States can simply ignore such clauses and not transpose them into national law, thus rendering them worthless. Second, differences between Member States in transcribing the law could lead to more, rather than less, variation in regulation and, in due course, constitute obstacles to trade. Either could result in the de facto failure of regulation and reports on the implementation of the TPD reveal that compliance has been problematic in some countries[340-341, 38]. This appears to reflect deficiencies in aspects of the directive itself, delays in providing technical and scientific guidance[340-341] and industry failure to comply[38]. It is clear that numerous problems remain with the current EU regulatory framework, within which tar and nicotine labels are highly misleading, consumers remain poorly informed about tobacco and nicotine products, and ingredients disclosure provisions are sub-optimal[38, 41, 36].

**Lobbying**

Despite divisions in the industry, its lobbying was comprehensive, carefully adapted to each stage of the directive’s passage and to the EU’s multiple fora. It made maximal use of national manufacturing associations, pan-European groups and potential allies such as trade unions and farmers, adapting both the message and the messenger to suit the audience. Thus, for example, various pan-industry groups (Table 3), and CECCM in particular, played a key role in Brussels, while national manufacturing

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**kk** Unsuccessful attempts were made to enshrine public health in the EU Constitutional Treaty (2004), a single instrument which repeals and replaces most of the existing treaties and are unlikely to occur in the near future, particularly considering that the new EU Constitution is undergoing a lengthy and fraught process of ratification.
associations featured heavily in member states and unions were encouraged and enabled to participate in both settings.

This comprehensive and multi-faceted strategy contrasts starkly with the 1991 description of PM’s European lobby as "understaffed, under experienced, disjointed and uncoordinated", reflecting both advice received at that time on how to lobby effectively in Europe and the substantial subsequent growth of the tobacco industry lobby[231, 1]. The diffuse nature of this lobby highlights the difficulties policy makers face in attempting to assess the veracity of the message and messenger in such debates and the complexity of accurately registering interest representatives, particularly when done on a voluntary basis[2]. This is further underlined by evidence from this and related studies[333, 172] of the industry’s use of think tanks, front groups and business groups such as the CBI to convey its messages, the limited transparency of some pan-industry organisations, notably in this instance Tobacco House, and evidence that BAT may have deliberately sought to underestimate its lobbying capacity in the register of interest representatives[1].

The high degree of institutional pluralism characteristic of EU policy-making facilitated a multi-pronged approach in which the resources available to the industry opened avenues that were effectively closed to the health lobby. This enabled tobacco companies, for example, to transport trade unionists to Strasbourg, Luxembourg and London and to publish and promote an “employment impact assessment”. By its very nature, therefore, this institutional complexity can be viewed as favouring more powerful and better resourced actors, as previous work on corporate influence in Europe suggests[342-346]. The documents indicate that it is also easier for major corporations to establish contacts at the highest political level, with BAT, for example, taking advantage of a meeting between the UK Prime Minister and the BAT chairman, the kind of privileged access available only to senior staff of leading corporations.

Efforts both to engage and threaten the Commission were, however, largely unsuccessful, thanks to the strong stance taken by Commissioner Byrne and his staff. Their awareness of industry tactics and excellent information base enabled them to rapidly rebut many industry arguments, including those relating to legal and economic issues. However, this contrasted with their apparent (and understandable) inexperience on scientific and technical issues, an area which provided an important window of opportunity for industry influence which was quickly seized. Using it to legitimise their presence at the policy table, the industry distracted the Commission with scientific minutiae and pushed PM’s preferred model of ingredient disclosure, which was briefly included in the directive’s text. Taking advantage of such inexperience to push industry-favourable legislation is not a new strategy[347-348] and without adequate safeguards can lead to regulatory capture[349]. Product regulation remains a
complex and contested area and this finding highlights the need for the Commission to have direct access to high level, independent scientific advice on any issues under consideration.

The industry enjoyed more success in the EP, where it focused on committee members and party leads, and targeted MEPs according to their political affiliations and interests. Well placed sympathetic contacts, most notably Lechner and Langer, German MEPs and rapporteurs for the Legal and Industry Committees respectively, played a key role. They tabled amendments at both Parliamentary readings that, had they been accepted, would have seriously weakened the directive. Although available documents do not demonstrate that the industry directly drafted these amendments, it clearly had close links to these MEPS (through the VdC), knew of the amendments they would propose in advance, and the amendments introduced were directly in line with key changes sought by the industry. Other MEPs played a role, with MEPs from the UK, the Netherlands, and Germany being most prominent, particularly those from regions with tobacco manufacturing jobs. Key to the directive’s passage in the Parliament, therefore, was the support of the Environment Committee and the careful negotiation of its rapporteur, Jules Maaten.

Similarities can also be observed between efforts to undermine the TPD and the EU Advertising Directive, including efforts to table industry favourable (and sometimes industry authored) amendments, although such tactics were used more covertly and with greater success against the Advertising Directive[4].

The industry also enjoyed some success in the CoM, where Germany again proved key and unaltering in its role as what can be termed a ‘veto state’[350]. National manufacturing associations were key to lobbying within member states and the powerful and well connected German tobacco manufacturers association, the VdC, again proved indispensable. It acted as a conduit of information from and to the German government, giving the industry privileged and timely access to information from Brussels, and directly informed the stance the German government took in the CoM. The VdC also had links with influential MEPs who tabled industry-favourable amendments. The key role of Germany and the VdC in influencing the TPD is in line with the role it played in industry efforts to influence the EU position on the FCTC[351] and the Advertising Directive[4].

Despite Germany’s support, the industry was unable to secure a blocking minority in the Council. A key issue here, which also proved essential in securing a majority for the earlier Advertising Directive[231], was the 1997 change in UK government, whereby a Conservative administration supportive of industry arguments[231, 4] was replaced by a new Labour government. Yet, despite the Labour government’s often strong position on tobacco control, represented in the White Paper, ‘Smoking Kills’[352], its relationship with tobacco companies remains complex. The TPD negotiations
coincided with both a DTI inquiry into cigarette smuggling and FCTC negotiations. Industry efforts to secure access to non-health ministries, notably the DTI, therefore served multiple purposes, albeit enjoying less success in relation to the TPD than to the smuggling enquiry, which, as the Guardian newspaper reports, was allegedly ‘buried’ following pressure on the Prime Minister and Stephen Byers at DTI[303]. Restricting the industry’s ability to secure a blocking minority will remain essential to the further development of EU tobacco control, and its capacity to do so has arguably been enhanced in the newly expanded union.

Splits in the industry

Although the industry initially presented a united front, splits gradually emerged between the individual companies that inevitably weakened the industry’s position. As PM had predicted, “lack of unity on important issues [means] low efficiency and credibility. Dissenting voices - industry is an easy target. Uniting the family is a must!”[93]. The key split was between PM and the other companies and was largely attributable to the fact that the directive represented a lesser threat to PM, as the market leader in Europe with minimum export production within Europe. Moreover, PM’s corporate makeover was already more advanced than that of its competitors and aggressively contesting the directive did not fit with its new image which involved presenting itself in a more responsible light[353, 108-109]. Since the tobacco industry has many common interests and often operates as a cartel[333], there is a tendency to treat “Big Tobacco” as a single actor. Yet, while companies have tended to act collectively on issues of joint concern, this has less frequently been observed in relation to taxation policy[354-355] and differences in corporate structure, market position, manufacturing location and brand portfolio will inevitably influence each company’s response to legislation. It is perhaps unsurprising therefore that the divisions observed between PM and the other companies in relation to the TPD, were also observed simultaneously over the FCTC[356, 351]. Such differences appear to be becoming entrenched, since PM is no longer a member of either CECCM[357] or the VdC, unlike other TTCs, while its efforts to support or encourage additional product regulation (often viewed as a means of further privileging its lead position) appear to be continuing[358-359].

5. 2 Implications for policy and practice

A number of issues that have implications for policy and practice emerge from this analysis. These are summarised below.

1. The industry’s concern with particular items in the directive, consistent with other evidence, suggests there are a number of issues the Commission should prioritise under current plans to revise the TPD. Notably, the industry’s concerns with large health warnings, indicates, in line with recent evidence on pictorial warnings[360-361], that large warnings are an effective tobacco control policy. The concern with misleading descriptors underlines the fact that such
Descriptors are central to the tobacco industry’s marketing efforts. Although the ban on misleading descriptors was enacted, the industry has continued to convey misleading messages through its packaging, thus undermining the directive[38]. Moreover, the industry’s previous focus on “light” cigarettes has now expanded to a broader focus on “innovation”[362], which includes a variety of new product features, such as charcoal filters (aimed again to reassure smokers) or short cigarettes (as a response to smoking bans to allow a quick smoke outside[363]. Recent industry presentations suggest that “light” cigarettes, like more recent cigarette innovations, are popular with young smokers and central to both volume and value growth for the industry[364-365]. Independent marketing reports concur, noting that innovative products have three purposes: to justify a premium price, to promise a different experience and to suggest reduced risk[363]. In reviewing the TPD the Commission may, therefore, wish to build on the achievements to date and the growing evidence base by, inter-alia, expanding the size of current health warnings, restricting the use of product innovations as it has the use of misleading descriptors, and exploring the role for plain or standardised packaging.\[8\]

2. The industry is willing to use arguments it has been advised are groundless. This underlines the need for the media and policymakers, including new incumbents, to be aware of industry tactics and to treat all industry arguments with extreme caution.

3. The willingness of the industry to misappropriate trade and legal arguments to support its cause highlights the need for those proposing and supporting tobacco regulation to be engaged in such debates. Effective health advocacy requires detailed familiarity with appropriate legal and trade opinions and engagement with non-health ministries (e.g. trade and finance) in garnering support for legislation. The cost of soliciting such opinions and supporting sufficient staff to access numerous ministries or directorates general may, however, be prohibitive to small public health groups. This, in addition to some of the points outlined below, raises the issue of appropriate funding for tobacco control groups in Europe, an issue that has been inadequately addressed since the closure of the Bureau for Action on Smoking Prevention (BASP) in 1995[366].

4. This report illustrates the complex ways in which the industry engages in lobbying, including the use of front groups to disguise its interests. Not only do policy makers need to be alert to such tactics, but critical monitoring of declarations from tobacco companies, pan-industry organisations and front groups in the new voluntary register will be essential to holding the

\[8\] It should be noted that, as part of its recommendations that led to the TPD, the Expert Committee had recommended generic packaging be implemented by 31\textsuperscript{st} December 2000[40] and that such a requirement would be in line with FCTC provisions.
industry to account\[1, 367\]. Ultimately, only obligatory disclosure is likely to prove sufficient to this task.

5. The TPD experience highlights key issues in shaping wider popular debate around tobacco control issues. The press articles recovered in this study largely reflected the industry’s economic arguments, overshadowing the public health gains; an imbalance that needs to be rectified in future debates. Trade unions can play a key role in lobbying and should be made aware of the true drivers behind EU tobacco factory closures and the way in which they have been used by the tobacco industry.

6. The industry’s ability to use economic arguments and business orientated impact assessments to its advantage must also be highlighted. This will have been further enhanced through the systematised approach to impact assessment that has subsequently been formally implemented in Europe\[177, 174-176\], at least partly as a result of tobacco industry lobbying\[172\]. Legislators and the public health community need to be aware of the industry’s reasons for pushing impact assessment, the pitfalls of such an approach and the need for accurate and independent data on economic impacts\[339, 172\]. This report makes it clear that relying on evidence submitted by the industry on such impacts is likely to be unacceptable. Evidence from the World Bank confirms that, in most industrialised countries, tobacco control measures would not lead to a net loss of jobs but rather to economic growth\[368\], yet this did not feature significantly in debates about the TPD. Such evidence still needs to be more widely circulated and taken into account in calculating economic impacts.

7. The industry’s ability to gain the upper hand on the scientific and technical aspects of the directive was attributable to the Commission’s understandable lack of internal expertise combined with a lack of access to clear, independent advice in this complex area. This highlights the need both for scientific consensus on these issues (the achievement of which may be facilitated by the FCTC process\[^\text{mm}\]) and ongoing access to expert advice from an early stage in the development of legislation which involves any complex scientific information.

8. The strong position taken by Commissioner Byrne and key members of his staff was essential to the directive’s success, highlighting the importance both of strong leadership and of Article 5.3 of the FCTC\[^{b}\] to successful EU tobacco control policy. Article 5.3, which takes into account the irreconcilable conflict between the tobacco industry’s and public health policy interests, aims

\[^{\text{mm}}\] Article 9 of the FCTC calls for internationally accepted guidelines for testing, measuring and regulating the contents and emissions of tobacco products, and Article 10 calls for regulation of tobacco product disclosure.
to protect public policy from industry interference[369-370]. If properly implemented, the recently developed guidelines on Article 5.3[370] should ensure that Commission staff are able to adopt a similarly robust position in future debates by requiring, *inter-alia*, that interactions with the tobacco industry are limited to those that are strictly necessary, that such interactions are conducted transparently and that information provided by the tobacco industry is transparent and accurate.

9. The national politics of tobacco control within member states are similarly crucial. As with the Commission, the position taken by the UK government in rebutting the industry’s advances was key – had the industry successfully influenced this member state, the Council may have rejected the directive. The role of Germany in seeking to undermine the directive was again central to industry strategy. Efforts to understand and curtail the influence of the industry in Germany will be critical to the success of future EU tobacco control policy. All EU member states bar the Czech Republic have now ratified the FCTC and Article 5.3 could, if properly implemented in Germany, have an impact. This is, however, unlikely to happen unless health advocates hold the German government firmly to account on this issue. Similar issues are likely to apply among the new member states, although their role in influencing tobacco control debates has yet to be formally examined.

10. Acknowledging and understanding divisions between individual tobacco companies could be advantageous to the health lobby, particularly since these are likely to increase as tobacco control regulations become more complex. Portraying cigarette manufacturers as ‘Big Tobacco’ has advantages from a public health perspective[371], not least in supporting efforts to delegitimise the industry, but recognition of strategic differences between companies may be important in understanding positions adopted on specific issues. Since effectively countering political strategies of tobacco companies is key to effective health regulation, the future development of tobacco control requires detailed understanding of their respective positions and priorities.

11. Tobacco control legislation must be carefully drafted to prevent any uncertainty in interpretation. In the case of the TPD this led not only to the application of misleading descriptors to products for export being overturned in the ECJ but to problems with implementation and enforcement.

12. Such limitations notwithstanding, the TPD constituted an important development within international tobacco control. Its attempts to regulate aspects of cigarette exports offered some recognition of the responsibility of countries hosting transnational tobacco companies amid the globalisation of the tobacco pandemic, a recognition that is absent from current USA proposals.
More importantly, its provisions for enlarged health warnings and the ban on misleading descriptors were highly influential in the development of the FCTC. The TPD contributed significantly to the international development of product regulation, a basis which the FCTC can now take forward.
6 APPENDICES

Appendix 1 Major EU tobacco control directives

(note that some of the earlier directives have been replaced by later directives as indicated in the table)

| Labelling and product regulation | 89/622/EEC | Tar and nicotine yield to be printed on the side and a health warning on the front of each cigarette pack in a clearly legible print with contrasting background. Each warning to cover 4% of the appropriate surface, 6% for countries with two official languages & 8% for countries with three official languages. Health warning to be applied also to tobacco products other than cigarettes but without specific criteria regarding clarity and legibility.
| 92/41/EEC | Amended Directive 89/662 by introducing a wider range of warnings for cigarettes and other tobacco products, and each warning in each language to cover at least 1% of the total surface of the unit packet for products other than cigarettes. Marketing of certain tobacco products for oral use banned.
| 90/239/EEC | Sets a maximum tar yield of 15mg per cigarette by 31st December 1992 and 12mg per cigarette from 31st December 1997.
| 2001/37/EC | Specifies a reduction in tar yield from 12 to 10mg, sets limits for nicotine (1mg) and carbon monoxide (10mg), health warnings to cover 30% of the pack front, additive and ingredient disclosure, a ban on misleading product descriptors such as “light” and “mild”. Derogations on tar yield for Bulgaria until Jan 2011.
| Taxation | 92/78/EEC | Set minimum levels of duty on cigarettes and tobacco.
| 92/79/EEC | Requires an overall excise duty (specific and ad valorem combined) of at least 57% of the final retail selling price of the price category most in demand, plus a VAT rate of 13.04%.
| 92/80/EEC | Introduces a fixed minimum amount of taxation expressed in Euros by requiring that the minimum excise rates outlined above shall be at least €60 per 1000 cigarettes for the price category most in demand.
| 95/59/EEC | 99/81/EC | 2002/10/EC |
| Advertising and sponsorship | 89/552/EEC | Bans all forms of TV broadcast and on-demand audio-visual media service advertising for tobacco products.
<table>
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<tbody>
<tr>
<td>Annulled October 2000</td>
<td>2003/33/EC</td>
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<tr>
<td>Directive on advertising of tobacco products</td>
<td></td>
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Source: Adapted from[372]

<table>
<thead>
<tr>
<th>Article in the final version 2001/37/EC (Article no. in original proposal COM(99)594 in parentheses)</th>
<th>Provisions accommodated in the final version 2001/37/EC</th>
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<tbody>
<tr>
<td><strong>1</strong></td>
<td><strong>Aim:</strong> to approximate the laws, regulations and administrative provisions of the Member States concerning the maximum tar, nicotine and carbon monoxide yields of cigarettes and the warnings regarding health and other products, together with certain measures containing the ingredients and descriptions of tobacco products, taking as a basis a high level of health protection</td>
</tr>
<tr>
<td><strong>2</strong></td>
<td><strong>Definitions including ingredients:</strong> any substance or any constituent except tobacco leaf and other natural or unprocessed tobacco plant parts used in the manufacture or preparation of a tobacco product and still present in the finished product, even if in altered form, including paper, filter, inks and adhesives</td>
</tr>
</tbody>
</table>
| **3** | **Cigarettes maximum yields**  
Tar (10mg), nicotine (1mg) and carbon monoxide (10mg)  
Derogation for application of yields for those manufactured in EU but sold outside  
Derogation for Greece for tar yields until 1 Jan 2007 (Article 4 in 1999 proposal) |
| **4 (Art 5)** | **Measurement methods** for tar, nicotine and carbon monoxide yields using specified ISO standards  
Tests carried out/verified by laboratories approved and monitored by MS  
MS send Commission a list of approved laboratories by 30 Sept 2002  
MS require manufacturers to carry out tests for yields on other substances by brand name and by type in order to assess health effects including addictiveness  
Test results should be submitted annually to MS  
MS ensure dissemination of information to consumers taking into account any information which constitutes a trade secret  
MS communicate all data and information submitted pursuant to this Article to the EC |
| **5 (Art 6)** | **Labelling:** yields on side of pack covering at least 10% with one language, 12% for two and 15% for three official languages  
Health warnings on tobacco product packets other than oral or smokeless tobacco to be on front and back. Single warning for smokeless tobacco products  
Warnings at least 30% on front - increased to 32% if two and 35% if three languages; and 40% on back of pack - increased to 45% with two and 50% if three languages  
Warnings and yields to be in Helvetic black bold type on white background, in a central areas  
Commission should adopt rules for colour photographs or other illustrations no later than 31 December 2002  
Product marked with batch number or equivalent for product identification and traceability |
| **6 (Art 7)** | **Further product information**  
List of all ingredients and quantities by brand and type with reason for inclusion,
function, category and toxicological data in burnt and unburnt form, and taking into account, inter alia, any additive effects

MS disseminate to consumers, taking into account protection of trade secrets

MS communicate all data to Commission

7 (Art 8) Product descriptions
Texts, names, trade marks and figures suggesting that the tobacco product is less harmful than others prohibited

8 (Art 9) Tobacco for oral use prohibited for sale in MS without prejudicing accession of Austria, Finland and Sweden

9 (Art 10) Adaptations
Commission will adapt to scientific and technical progress in measurement methods, health warnings and markings for identification and tracing purposes of tobacco products

10 Commission shall be assisted by a committee

11 (Art 10) Report by 31st December 2004 and every two years thereafter the Commission shall submit a report on the application of the directive, with assistance from scientific and technical experts

In the first report the Commission shall indicate which features should be reviewed or developed, in light of scientific or technical knowledge, including the development of internationally agreed rules and standards on products, with special attention to, inter alia:

- reduction of maximum yields
- Links between these yields
- Labelling and pictures
- Methods for realistically assessing and regulating toxic exposure and toxicology of ingredients
- Evaluation of addictive effects of ingredients
- Evaluation of ‘reduced harm’ products
- Standardised testing methods to measure yields of smoke constituents other than tar, nicotine and carbon monoxide
- Standards for non cigarette products, such as rolling tobacco

12 Common list of ingredients
Commission invited, via first report, to propose a common list of ingredients authorised for tobacco products, taking into account, inter alia, their addictiveness

13 (Art 11) Import, sale and consumption of tobacco products
MS cannot prohibit or restrict the import, sale or consumption of tobacco products which comply with the directive

MS can still introduce more stringent rules in accordance with the Treaty which they deem necessary to protect public health

MS may in particular provide for the prohibition, pending the establishment of the common list of ingredients, of the use of ingredients which increase the addictiveness of tobacco products

14 (Art 12) Implementation
Comply by 30th September 2002
Non compliant cigarette products can be marketed for one year after
Non compliant products other than cigarettes can be marketed for two years after
MS communicate the text of the domestic law provisions to the Commission

15 (Art 13) Repeal of Directives 89/622/EEC and 90/239/EEC

16 (Art 14) Entry into force on day of publication in the Official Journal of the European Communities

17 (Art 15) Addressees: MS
Appendix 3: The EU institutions and origins of the co-decision procedure

The EU consists of a number of institutions. The European Commission acts as the executive and drafts legislative proposals following consultation with experts drawn from the Member States and advisory committees. The Commission comprises several DGs and Commissioners. Tobacco control is the responsibility of DG SANCO. The EP and the CoM are the legislative bodies; the former consists of elected MEPs and the latter, ministers from national governments.

The smooth running of the Council is dependent on the preliminary negotiations performed by the Member State’s Ambassadors to the EU in the Committee of Permanent Representatives (known as COREPER) and the Council Working Groups. After several iterations of negotiations in these ‘closed’ meetings, the Council formally meets and votes on a proposal. Other parliamentary committees also exist, e.g. the Legal Affairs and Internal Market Committee (JURI), the Agriculture and Rural Affairs Committee (AGRI) the European Economic and Social Committee (EESC) and the Committee of the Regions (CoR). These are consulted on proposed legislation if it falls within their remits. The ECJ serves as a “guardian of the treaties”[231](p221) through its judicial scrutiny of Community action.

The co-decision procedure, which gives the EP the power to adopt instruments jointly with the Council on certain issues, came into force at Maastricht (Article 251)[18]. Prior to that MEPs were merely consulted on legislation. The Amsterdam Treaty (1999)[373] strengthened Parliament’s scrutinising role and extended its scope to new areas like public health. Qualified majority voting in the Council (where a population-weighted number of votes is allocated to each Member State) was introduced by the Single European Act (1986)[374] and extended under Maastricht (1992)[19]. This has now become the general voting procedure, replacing unanimity which carried a higher veto risk and thus lower legislative output.
Appendix 4: Article 95

Items of relevance that feature in Section 4.2.1 are underlined

1. By way of derogation from Article 94 and save where otherwise provided in this Treaty, the following provisions shall apply for the achievement of the objectives set out in Article 14. The Council shall, acting in accordance with the procedure referred to in Article 251 and after consulting the ECOSOC, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

2. Paragraph 1 shall not apply to fiscal provisions, to those relating to the free movement of persons nor to those relating to the rights and interests of employed persons.

3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.

4. If, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 30, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.

5. Moreover, without prejudice to paragraph 4, if, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.

6. The Commission shall, within six months of the notifications as referred to in paragraphs 4 and 5, approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.

In the absence of a decision by the Commission within this period the national provisions referred to in paragraphs 4 and 5 shall be deemed to have been approved. When justified by the complexity of the matter and in the absence of danger for human health, the Commission may notify the Member State concerned that the period referred to in this paragraph may be extended for a further period of up to six months.

7. When, pursuant to paragraph 6, a Member State is authorised to maintain or introduce national provisions derogating from a harmonisation measure, the Commission shall immediately examine whether to propose an adaptation to that measure.

8. When a Member State raises a specific problem on public health in a field which has been the subject of prior harmonisation measures, it shall bring it to the attention of the Commission which shall immediately examine whether to propose appropriate measures to the Council.

9. By way of derogation from the procedure laid down in Articles 226 and 227, the Commission and any Member State may bring the matter directly before the Court of Justice if it considers that another Member State is making improper use of the powers provided for in this Article.

10. The harmonisation measures referred to above shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 30, provisional measures subject to a Community control procedure.
Appendix 5: How to search for tobacco industry documents

Following a series of litigation cases in the US, leading tobacco companies were required to make internal documents public[56]. These are now available online at the following website: http://www.legacy-library.ucsf.edu which is free and can be accessed by anyone with an interest in the documents. This online library allows users to search the documents using optical character recognition (i.e. the search facility can be used to search for specific words and phrases),[60] although hand-written or faint documents, or those with typographical errors and spelling mistakes, may not always be picked up this way. Every page of the documents also has a unique identification number, known as a Bates number, and the online library also allows users to search consecutive Bates numbers (which, due to the way the documents were collated and scanned, often allows researchers to search through whole company folders on specific topics). To help focus searches, Boolean operators and date restrictions can be used, and it is also possible to focus searches on the documents obtained from individual tobacco companies. The documents provide a crucial resource for those interested in studying the tobacco industry and, due to their broad coverage, also provide insights into the lobbying efforts of companies that worked with the tobacco industry, providing a unique resource for analysing corporate strategy and conduct more generally.
7 References (Documents last accessed on 27 April 2012 unless otherwise stated)


43.Pollay R W, Dewhirst T. The dark side of marketing seemingly "Light" cigarettes: successful images and failed fact. *Tob Control* 2002; 11 i18-31. [http://tobaccocontrol.bmj.com/content/11/suppl_1/i18.abstract](http://tobaccocontrol.bmj.com/content/11/suppl_1/i18.abstract)


64. Strategic issues task force recommendations specific implementation steps for product regulation table of contents1999. Philip Morris. 2078746599. [http://legacy.library.ucsf.edu/tid/vqa82c00](http://legacy.library.ucsf.edu/tid/vqa82c00)


69. Japan Tobacco. DG SANCO. 2000. RJ Reynolds. 528397839/7864. [http://legacy.library.ucsf.edu/tid/ghi93a00](http://legacy.library.ucsf.edu/tid/ghi93a00)

70. Bruckner E. VdC. Concerning EU polcy on tobacco products. 1999. RJ Reynolds. 521518769/8771. [http://legacy.library.ucsf.edu/tid/gqc01d00](http://legacy.library.ucsf.edu/tid/gqc01d00)


75. Dembach W. Telefax Follow-up after Meeting with the Commission on 001123. 1999. Philip Morris. 2071982370/2371. [http://legacy.library.ucsf.edu/tid/kbv32c00](http://legacy.library.ucsf.edu/tid/kbv32c00)


138. Smoke-Free Europe Conference on Tobacco or Health Helsinki, Finland 961002 - 951004. 1996. Philip Morris. 2065249605/9637. [http://legacy.library.ucsf.edu/tid/umb60b00]


144. European Parliament legislative resolution on the Council common position for adopting a European Parliament and Council directive on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products (9448/1/2000 - C5-0431/2000 - 1999/0244(COD)). _Official Journal of the European Communities_. C 232; 44. (http://www.europarl.europa.eu/pv2/pv2?PRG=DOCPV&APP=PV2&LANGUE=EN&SDOCTYPE=7 &TXTLST=1&POS=1&Doc=RESOL&TPV=DEF&DATE=131200&PrvType=PRODUCT@A5&PG@QUERY&APP=PV2&FILE=CONTENT@BIBLIO00&NUMERO@348&YEAR@2000&PLAGE@1&TYPEF=A5 &NUMB=1&DATREF=001213).


84
156. Callard C, Chitanondh H, Weissman R. Why trade and investment liberalisation may threaten effective tobacco control efforts. *Tob Control* 2001; 10 (1): 68-70. [http://tobaccocontrol.bmj.com/content/10/1/68.full](http://tobaccocontrol.bmj.com/content/10/1/68.full)


158. Chantornvong S, McCargo D. Political economy of tobacco control in Thailand. *Tob Control* 2001; 10 (1): 48-54. [http://tobaccocontrol.bmj.com/cgi/content/abstract/10/1/48](http://tobaccocontrol.bmj.com/cgi/content/abstract/10/1/48)


http://legacy.library.ucsf.edu/tid/eua54a99


   http://www.hm-treasury.gov.uk/d/433.pdf

205. House of Commons, Committee of Public Accounts. Press Notice No. 3 of Session 2002-03, dated 10 January 2003


222. Dembach W, Dutreix G. 2000. Philip Morris. 2072266665/6666 http://legacy.library.ucsf.edu/tid/cki06c00


266. Muller L. First draft of talking points for the presentation to Mr Ryan et al. 2000. Philip Morris. 2075165805/814. http://legacy.library.ucsf.edu/tid/gab27d00


http://bat.library.ucsf.edu//tid/fbt72a99

http://bat.library.ucsf.edu//tid/xtx44a99

http://legacy.library.ucsf.edu/tid/jfn00a99

http://legacy.library.ucsf.edu/tid/zah87a99

http://legacy.library.ucsf.edu/tid/xpc30a99

http://legacy.library.ucsf.edu/tid/ffi08a99

290. ASH. Tobacco ad ban passes last but one hurdle - but Hague's 'new' Conservatives still doing the tobacco industry's dirty business. Press release. 22 April 1998
http://www.ash.org.uk/ash_fwcczhaj.htm

http://legacy.library.ucsf.edu/tid/tjr10a99

http://legacy.library.ucsf.edu/tid/wbh02a99


http://bat.library.ucsf.edu//tid/vph45a99


http://www.publications.parliament.uk/pa/cm199900/cmselect/cmhealth/27/2702.htm

http://bat.library.ucsf.edu//tid/coi61a99

http://bat.library.ucsf.edu//tid/doi61a99

http://bat.library.ucsf.edu//tid/agw80a99

93


311. Grüning T, Strünck C, Gilmore A. Puffing away? Politics of tobacco control in Germany. German Politics 2008; 17 140-64 http://dx.doi.org/10.1080/09644000802075708


95


333. WHO. Tobacco industry interference with tobacco control. WHO. Geneva. 2008


345. Eising R. The access of business interests to EU institutions: notes towards a theory. Centre for European Studies, University of Oslo. Oslo. 2005 [http://www.arena.uio.no](http://www.arena.uio.no)


357. CCECM. Confederation of European Community Cigarette Manufacturers 2009 [http://www.ceccm.eu/members.html](http://www.ceccm.eu/members.html)


370. WHO. "Guidelines for implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control on the protection of public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry." Paper presented at the Conference of the Parties to the FCTC, 2008. [http://www.who.int/fctc/guidelines/article_5_3.pdf](http://www.who.int/fctc/guidelines/article_5_3.pdf)

371. Wander N. A gentlemen’s disagreement: Cooperation versus competition among transnational tobacco companies. In *14th World Conference on Tobacco Or Health*. Mumbai, India, 2009
