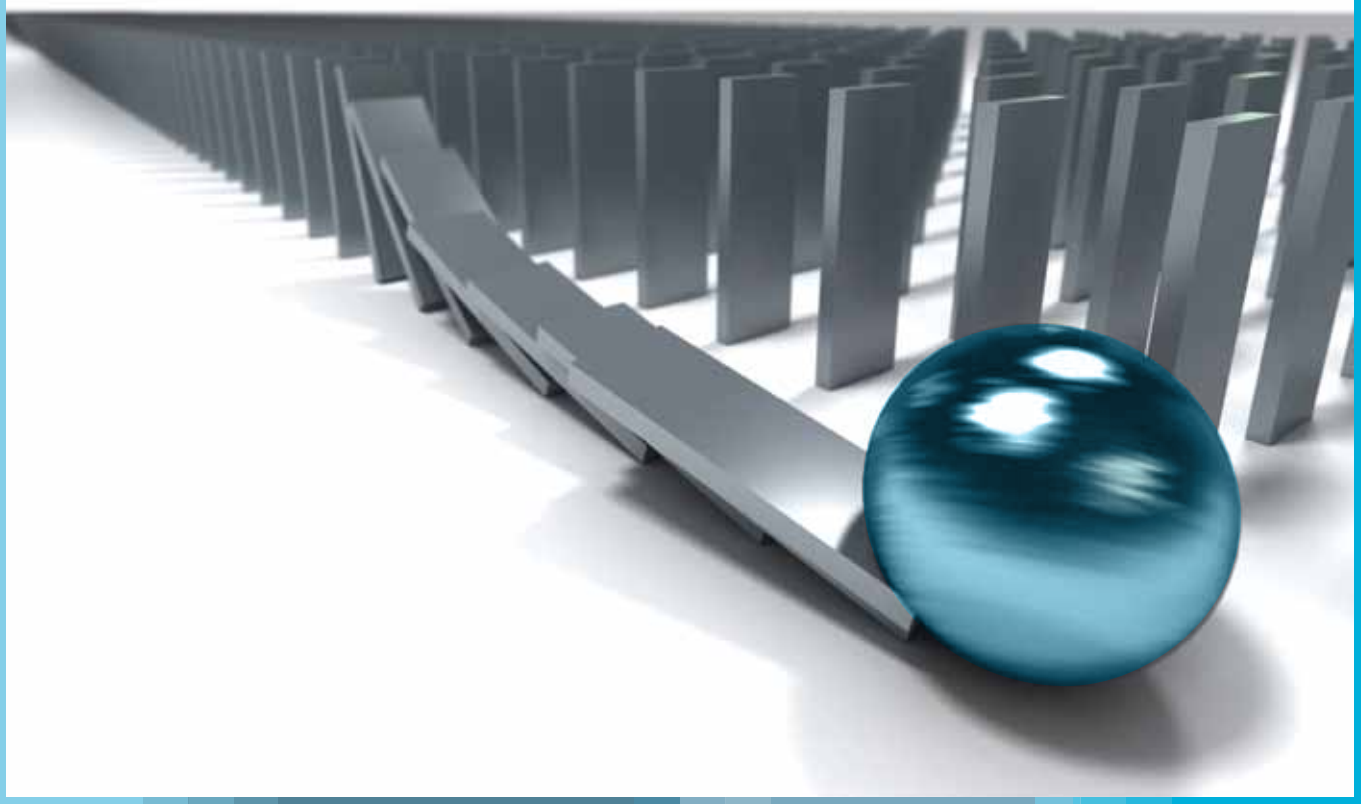
The Origin of EU Better Regulation - The Disturbing Truth



SMOKEFREE PARTNERSHIP
A world without tobacco

Index

‘Better Regulation’ – Better for Whom? A summary of new research

'Better Regulation' – Better for Whom? A summary of new research

Executive Summary

In the past decade, a series of regulatory reforms, known as Better Regulation (see **Box 1**), has been adopted across Europe, marking a significant shift in the way policies are developed.[1,2] Recently described as *'one of the most fashionable terms circulating in the corridors in Brussels'*,[1] Better Regulation has been promoted as a means of improving policymaking in the public interest. The concept is widely supported by many Member States[3,4] and at EU level it is deemed to be so important that European Commission President, Jose Manuel Barroso, recently announced his decision to personally oversee its implementation.[5] The ratification of the Treaty of Lisbon,[6] with its emphasis on economic growth and competitiveness, has provided further impetus for the Better Regulation agenda, which is widely perceived to be business friendly.[7] Yet, little is known about the extent to which business interests have actually shaped this agenda. New research, based on an analysis of previously secret documents which tobacco companies were forced to release as a result of litigation[8], demonstrates that British American Tobacco (BAT) and a number of other large corporations played a key part in promoting the regulatory reforms within the EU that together comprise Better Regulation (see **Box 1**). The documents show that they actively pushed for these reforms because it would seem they anticipated that they would favour their corporate interests over social and environmental concerns. These findings: (a) raise serious concerns about the extent of corporate influence in the EU and the ways in which this influence has been formalised; (b) indicate the direction and impact of regulatory reform in the EU may pose a threat to public health and the environment; and (c) suggest that, whilst the regulatory burden on business may be declining, it is being replaced by a growing administrative burden on EU officials, at taxpayers' expense.

Three enclosed research briefings summarise these findings, revealing how BAT and the other corporations with which it worked have driven forward EU reforms on impact assessment, risk assessment and stakeholder consultation.They explain what BAT hoped to achieve, why senior managers at the company believed these policy changes would work in the company's favour and how they then managed to successfully alter the rules by which EU policy is made. This included securing changes to the Treaty of Amsterdam which made a form of Impact Assessment mandatory, an achievement which an internal BAT document describes as 'an important victory' for the company[9].

Box 1: What is Better Regulation?

Better Regulation describes a programme of regulatory reform taking place at EU and Member State level, which has been informed by similar, earlier reforms in the US. The term Better Regulation is vague and has been interpreted in a variety of ways but it is frequently associated with a desire to achieve a 'simplified' regulatory environment in which formal intervention is limited and 'self-regulation' and 'co-regulation' are considered as alternatives. In the EU, this has been reinforced by a specific commitment to reducing regulatory costs to business by 25%. It is possible to identify three core themes of Better Regulation, each of which feeds into the overall aim of achieving less of a regulatory burden on business:

(i) The increased use of impact assessment, most notably an economic oriented form of impact assessment which aims to ensure policymaking does not impact negatively on business competitiveness (see *Research Briefing 1: Impact Assessment – A Threat to Human Health in the EU?).*

(ii) The increased use of risk assessment, to assess whether or not regulatory intervention is required (see *Research Briefing 2: The Risks in Risk Assessment).*

(iii) A commitment to early dialogue between regulator and regulated (see R*esearch Briefing 3: Stakeholder Consultation, Regulatory Capture and the 'Good Governance' Trap).*

The findings demonstrate that:

- From the mid-1990s, BAT recognised that risk assessments and business impact assessments could be manipulated to further the interests of the tobacco industry. Senior managers at BAT believed that a particular form of risk assessment would help prevent the introduction of tobacco control regulations, particularly smoke free legislation, and that business impact assessments could help deter the introduction of regulation more generally and ensure industry involvement at an early stage of the policymaking process (thereby increasing the potential for influencing policy outcomes).

- BAT subsequently began actively pushing for risk assessment and business impact assessments within EU policymaking and specifically sought to make business impact assessment a legal requirement by

working with others to secure changes to the Treaty of Amsterdam.

- To this end, BAT worked closely with the European Policy Centre and the Fair Regulation Campaign and helped to recruit a coalition of supportive companies in other sectors. These various groups then lobbied Member States, the Commission, MEPs and others to obtain the desired changes.

- By 1997, BAT and the European Policy Centre had secured changes to the Treaty of Amsterdam that mandate both 'wide' consultation and the assessment of costs to 'economic operators' (i.e. a form of business impact assessment).

- BAT and its allies then worked to ensure that these changes were embedded in EU policymaking processes in a way that would work to their advantage.

- They secured the support of a number of Commissioners who helped drive forward work on business impact assessments and consultation with industry, culminating in the publication of official guidelines on stakeholder consultation[10] which are now being used to justify ongoing consultation with industry. In the case of the tobacco this is continuing despite the fact the EU has ratified a global public health treaty which includes measures intended to protect public health policies from undue tobacco industry interference.

- Throughout, BAT's involvement in the push for regulatory reform in the EU has been far from transparent, obscured by the cover of think tanks, campaign groups and consultancy firms.

- The campaign remains ongoing and currently appears to be focusing on efforts to change policymakers' understandings of, and responses to, perceived risks (particularly to human health and the environment).

Conclusions and implications for policy

Whilst the principles of Better Regulation, as promoted by the Commission, are intended to ensure EU policy works in the public interest, the agenda has been cleverly manipulated by corporate interests to the extent that this may no longer be the case.

The research highlights the extent of corporate influence in the EU and demonstrates how this has been formalised through the various components of Better Regulation.

Without serious consideration, Better Regulation could therefore, just as it seems the corporations involved intended, work to ensure policies that act in business' interest are more likely to succeed than policies required to protect population health or the environment.

Whilst the regulatory burden on corporations on business is being reduced, this has been replaced by an increasingly onerous burden on the European Commission, at taxpayers' expense.
The Commission needs to be aware of these issues and rethink the Better Regulation agenda to ensure that it works in the public's interest. This requires that:

(i) Impact assessment and risk assessment processes are accurately and fairly examined, in a way that does not prioritise one sector's interests over another's.

(ii) Consultation processes are fair and transparent, acknowledging documented evidence that corporations often act through third parties. In the case of tobacco, consultation processes also need to be consistent with the World Health Organisation international Treaty that the Commission has ratified.

(iii) Efforts to reduce regulatory and administrative burdens should focus on overall burdens (including those carried by EU officials) and not just on the burdens imposed on businesses.

References:

1 Allio, L. (2007). Better regulation and impact assessment in the European Commission. In C. Kirkpatrick & D. Parker (Eds.), *Regulatory Impact Assessment - Towards Better Regulation?* Cheltenham: Edward Elgar Publishing, 72-105.

2 Commission of the European Communities. (2005). Communication from the Commission to the Council and the European Parliament - Better Regulation for Growth and Jobs in the European Union (SEC(2005) 175). Brussels. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2005:0097:FIN:EN:PDF (accessed 06 Apr 2009): Commission of the European Communities.

3 BERR. (2007). *Next Steps on Regulatory Reform.* London. http://www.berr.gov.uk/files/file44370.pdf (accessed 06 Apr 2009): Department for Business, Enterprise & Regulatory Reform (BERR).

4 Department of the Taoiseach. (2004). *Regulating Better - A Government White Paper setting out six principles of Better Regulation.* Dublin. http://www.betterregulation.ie/attached_files/upload/static/RegulatingBetterGovernmentWhitePaper.pdf (accessed 06 Apr 2009): Department of the Taoiseach.

5 EurActive.com (2009) 'Barroso seizes control of 'Better Regulation' agenda'. Published on 21 Sep 2009 at: http://www.euractiv.com/en/opinion/barroso-seizes-control-better-regulation-agenda/article-185603 (accessed 18 Nov 2009).

6 European Communities (2007) Treaty of Lisbon Amending the Treaty on European Union, the Treaties establishing the European Communities. Brussels: Office for

Official Publications of the European Communities and Europa: http://www.europarl.europa.eu/lisbon_treaty/full_text/index_en.htm (accessed on 19 Nov 2009).

7 BusinessEurope (2009) 'European Reform Barometer - Spring 2009 Reforms are a vital pillar of the recovery' URL: http://212.3.246.117/docs/1/ABLFCHDCGMLLKMBJNDDHILNDPDBG9DBNG69LTE4Q/UNICE/docs/DLS/2009-00643-E.pdf (accessed 19 Nov 09).

8 Following a series of litigation cases in the US, leading tobacco companies were required to make internal documents public. 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.

9 BAT. (Undated). Shaping the Regulatory Environment: Advertising and Public Smoking. (Bates number(s): 322121140-322121143). Source: BAT. URL: http://bat.library.ucsf.edu//tid/xnz82a99 (accessed 23 May 2008).

10 Commission of the European Communities. (2002). Towards a reinforced culture of consultation and dialogue - General principles and minimum standards for consultation of interested parties by the Commission (COM(2002) 704 final): http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0704:FIN:EN:PDF <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0704:FIN:EN:PDF> (accessed 26 Aug 2008).

Research Briefing 1:
Impact Assessment (IA) –
A Threat to Human Health in the EU?

Research Briefing 1: Impact Assessment (IA) – A Threat to Human Health in the EU?

Executive Summary

New research shows that major corporations, led by British American Tobacco (BAT), secured changes to EU legislation via the Treaty of Amsterdam that fundamentally altered the way all EU policy is made by making a business-oriented form of impact assessment mandatory. Aided by think tanks and lobbyists, the corporations involved recognised that business impact assessment would work to their advantage by:

- providing an economic framework for evaluating all EU policy decisions (implicitly prioritising costs to businesses);
- securing early corporate involvement in policy discussions;
- advancing corporate policy influence over the interests of other sectors by increasing policymakers' dependence on information supplied and owned by businesses;
- providing corporations with a persuasive means of challenging legislation.

As a result of this campaign, all significant EU policy decisions now have to be considered through an impact assessment framework which, by focusing heavily on business and economic impacts, provides large businesses with a number of advantages over other policy actors, just as the corporations involved intended. The consequence is an increased likelihood that the EU will produce policies that advance the interests of major corporations rather than its citizens. This briefing summarises the EU's current approach to IA, explains how it emerged as a result of industry pressure and, whilst recognising the important contribution IA can potentially make to decision-making processes, outlines the dangers inherent in this approach, notably that it can systematically advantage corporate interests and potentially threaten health. It concludes by outlining the key conclusions and implications for policy.

How does IA work in the European Union?

In the past, several different forms of IA (see **Box 1**), including Business Impact Assessment (BIA)[a], Health Impact Assessment (HIA) and Environmental Impact Assessment (EIA) were used by different parts of the Commission, depending on the primary focus of each Directorate-General. However, in 2002, the Commission established a new 'integrated' IA system, which aimed to bring these various forms of IA together. The integrated system encourages policymakers to attach a monetary value to each predicted impact and then total all the 'costs' and 'benefits' (in other words, the EU's IA system is a form of cost-benefit analysis). The guidelines for the Commission's IA system have been revised several times since 2002 (most recently in 2009) and IA is now a compulsory part of the European policymaking process for virtually all Commission initiatives.[1]

a The Commission had been committed to using a relatively weak form of BIA since the late 1980s but, in practice, this early form of BIA made little difference to EU decision-making processes.

Box 1 - What is Impact Assessment (IA)?

IA is a means of assessing the impacts of policy options in order to inform decision-making processes. Different forms of IA focus on different types of impact (e.g. HIA, BIA and EIA) and some attempt to assess multiple impacts. IAs also vary in the ways in which they measure potential impacts. For example, some approaches merely try to collate information about various types of impacts, whilst others involve the quantification and monetisation of all impacts, which requires prices to be attached to all impacts that could be affected by a policy, including impacts on non-market goods that are difficult to quantify in this way, such as loss of life or health. When applied to the regulation of substances which pose threats to human health and/or the environment (e.g. tobacco or toxic chemicals), IA provides a framework for making decisions about whether and how policymakers should limit the resulting health and/or environmental damage. As such, IA sometimes incorporates risk assessment (see Research Briefing 2).

Does the Commission assess *all* impacts?

Although the Commission's current guidelines for IA require impacts to be assessed across three 'pillars' - economic, environmental and social - independent assessments of IAs produced by the Commission claim coverage across the three pillars is uneven, with economic impacts receiving the most attention.[2,3] Although some aspects of health are included under the 'social' pillar,[4] health impacts have received particularly limited attention in the Commission's IAs to date.[4,5] A review of all IAs carried out by the European Commission in 2005 and 2006 found that more than half did not even mention the word 'health'.[6] This is despite the

fact that Article 152 of the Treaty on European Union explicitly states that *"a high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities,"*[7] a statement that has been interpreted as requiring HIA for all EU policies.[8]

How did the economically orientated form of IA used by the Commission come about?

New research provides insights into how this bias may have come about. It demonstrates that the system of IA in the EU has been significantly shaped and promoted by a coalition of large corporations in regulated sectors. The campaign was led by the world's second largest transnational tobacco company, British American Tobacco (BAT), because senior managers at BAT believed such a system could work substantially in the tobacco industry's favour. Specifically, BAT believed BIA could help prevent bans on tobacco advertising[9] and pave the way for embedding consultation with corporations (see Research Briefing 3) and a form of risk assessment that would act in their interests (see Research Briefings 2) and, in 1995-1996, began to consider how they might promote these regulatory reforms. The process was complex and involved the following stages:

(i) Recruiting other companies and working through 'front groups'

BAT was aware that a campaign for regulatory reform that was known to be connected to the tobacco industry was unlikely to succeed[10] and was advised to work through a 'front group' and to recruit other companies with similar interests (such as other large companies in regulated sectors).[11] Following this advice, BAT approached the **European Policy Centr**e (EPC, a Brussels based think tank) to lobby for regulatory reforms on its behalf, and jointly they set about recruiting other business interests to this campaign.[12]

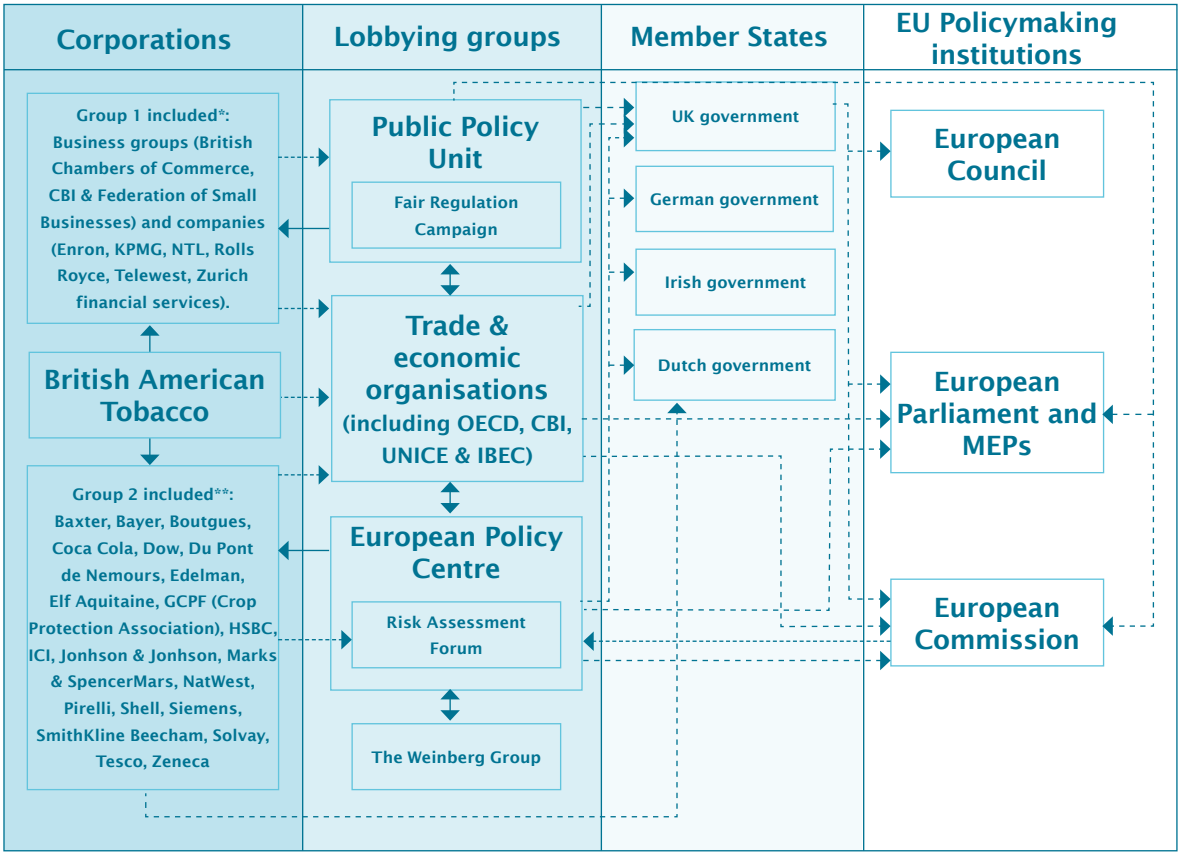
(ii) Securing a legal requirement for BIA in the Treaty of Amsterdam

Fronted by the EPC, and working with various other business organisations (such as the Union of Industrial and Employers' Confederations of Europe, UNICE, now rebranded BusinessEurope, and the Confederation of British Industry), the companies involved quickly established a highly influential lobbying campaign that, within 18 months, secured changes to the EU Treaty, obligating the Commission to 'consult widely' and minimise the potential 'burden' of policy changes on 'economic operators' (and others).[7] This was interpreted by BAT to mean that a form of BIA was now mandatory within EU policymaking, a development the company perceived as *'an important victory'* (see **Box 2**).

(iii) Creating a supportive policy network and embedding the policy changes

To ensure that the Treaty led to actual changes in the way policy decisions were made, BAT worked with the EPC to recruit more companies to what was by now called the EPC Risk Assessment Forum and helped establish an additional pressure group, the **Fair Regulation Campaign,** which also promoted the need for BIA and related regulatory reforms.[12] Policymakers were successfully targeted by both groups. The EPC, for example, persuaded the UK Presidency of the EU to officially sanction a conference that was paid for by BAT (something which may not have been disclosed to the policymakers involved) and which was used to promote BIA and RA. The various different initiatives undertaken by the EPC, the Fair Regulation Campaign and the business organisations they worked with, combined with the decision to target amenable Member States, all helped create the illusion that the pressure for regulatory reform in the EU was significant and diverse (see **Figure 1**).[12]

FIGURE 1: THE MULTIFACETED APPROACH TO LOBBYING TO SECURING BIA

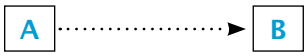


** Based on documents which reveal the companies involved in Fair Regulation Campaign meetings and email discussions.*[13,14]

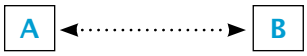
*** Based on both on documents which clearly outline which companies were members of the EPC Risk Assessment Forum and on companies' participation in Forum events.*[15,16,17,18,19,20,21]

KEY T FIGURE 1:

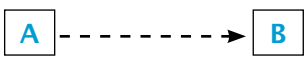
A lobbied B (where A represents multiple organisations, 1 or more members of A lobbied B)



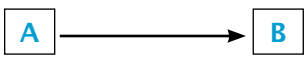
A and B lobbied one another



A was a member of / funded B



A helped recruit / worked with



(iv) Ensuring business inclusion at an early stage of policy discussions

The campaign for regulatory reform also sought to promote consultation with affected stakeholders, notably the business community, as an integral part of BIA and as a means of increasing 'transparency' in the EU.[22] For the business sector generally, this ambition appears to have been realised (see Research Briefing 3).

How the EU's approach to IA favours corporate interests

This research suggests the decision to focus on particular impacts (and not others) within the EU's IA system was political, not scientific, and emerged as a result of persistent (often covert) industry lobbying. The political nature of IA (given the necessary decision to ask some questions and not others) and the major uncertainties inherent in IA methodologies (particularly those which require non-market goods to be assessed in monetary terms, as the current EU system does) leave IA open to abuse. A growing body of academic literature suggests there are at least Seven Potential Dangers of IA that serve to systematically advantage corporate interests,[23] some of which are summarised in **Box 3**, yet most European policymakers appear unaware of these concerns, as **Box 4** illustrates.

Box 2: In their own words – how BAT influenced the Treaty of Amsterdam and fundamentally changed EU policymaking (the following is taken directly from an internal BAT document[9]):

The opportunity

In no country in the world are governments required, in practice, to justify their actions through effective cost-benefit analysis, underpinned by rigorous risk assessment. An opportunity to promote such a requirement was identified in the European Union (EU).

The Treaty of the EU does not currently contain any general requirement that government authorities carry out a cost-benefit analysis or structured risk assessment before imposing legislation. However, the EU Treaty was re-negotiated in June 1997 at the Intergovernmental Conference.

British American Tobacco and BAT Industries recognised that a broad coalition of like-minded companies might be able to persuade member states into amending the Treaty, imposing a binding requirement for cost benefit analysis and risk assessment.

The strategy

British American Tobacco and BAT Industries assembled a group of companies with a common interest in rigorous cost benefit analysis and risk assessment.

Supported by a public affairs consultant (European Policy Centre) and a technical consultancy (Weinberg Group), this ad hoc group of companies used its contacts and influence to promote the cause of cost benefit analysis and risk assessment.

Throughout late 1996 and 1997, the campaign gained momentum through lobbies of member state governments, companies, trade organisations, the European Commission and others.

Germany, the UK, Ireland and the Netherlands (who held the EU Presidency) were identified as the key players and lobbying focused on interests in those states. […]

The outcome

The new Treaty of the EU includes a (legally binding) Protocol on subsidiarity (the need to push decision making as far down as possible). Chapter 9 states: Without prejudice to its right of initiative, the Commission should:

· Except in cases of particular urgency or confidentiality, consult widely before proposing legislation and wherever appropriate, publish consultation documents; […]

· take duly into account the need for any burden, whether financial or administrative, falling upon the Community, national governments, local authorities, economic operators and citizens to be minimised and proportionate to the objective to be achieved; […]

So, the Commission must now take into account the financial and administrative burden (cost), which has to be minimised and proportionate to the objective (benefit).

Next steps (in Europe)

A framework now exists in the EU which demands cost benefit analysis and risk assessment.

The new Treaty comes into force in January 1999. Between now and then it is vital that pressure is kept up to ensure that the EU does not get off the hook and that the new Protocol is translated into a meaningful system of regulation. […]

Next steps at British American Tobacco
British American Tobacco has achieved an important victory in a key trade bloc. A priority should now be to encourage and empower other parts of the world to embark on similar exercises. […]

Box 3: IA – Deadly Concerns

1. Putting a price on life and providing a misleading sense of certainty

It is often impossible to know what the impacts of high-level policies will be in advance of their implementation, so the results of IAs are often uncertain. This is particularly true where non-market goods (such as human health or the environment) are involved because it is difficult to agree what the monetary value of such impacts is and because it is harder to predict the long-term impacts on health and the environment than the short-term impacts on business. Such issues are often obscured by IAs, resulting in a misleading sense of certainty.

2. Creating a policy dependence on vested interests

IAs can create a policy dependence on vested interests in the following ways:

(i) The EU's IA process is understood to require the Commission to consult 'interested parties' and has led to greater consultation with affected stakeholders about potential policy changes.[22] While this can improve the democracy and transparency of decision-making, consultation with businesses with a history of manipulating policy outcomes through covert means, such as the tobacco and chemical industries,[25,26,27] may work against policies designed to safeguard public health. This problem is exacerbated by the fact that less well resourced actors may be unaware of, or unable to fully participate in, consultation processes.

(ii) Even without the increased emphasis on consultation, much of the information required to undertake IA is owned by businesses (e.g. information relating to the likely impacts on business and the economy). Given that businesses are commercial organisations, it is rational for them to selectively disclose (or even manipulate) information that will work in their favour and recent evidence demonstrates that chemical companies have done precisely this (see **Box 4**).

(iii) Undertaking IAs is resource intensive and the Commission's limited resources mean it is not always possible for IAs to be produced internally. This increases the Commission's dependence on external (often commercial) consultants,[24] which is problematic if such firms are simultaneously working for vested interests, a situation which has already occurred (see **Box 4**).

3. Shifting the 'burden of proof' onto regulators whilst simultaneously undermining the evidence

Commentators with links to regulated industries argue that IA represents a scientific alternative to the precautionary principle (see Research Briefing 2). Such claims aim to shift the burden of proof away from manufacturers of risky goods towards the EU officials responsible for managing these risks, ensuring officials cannot prevent a risk until they can provide sufficient evidence to demonstrate the extent of that risk. This means that, whilst the regulatory burden on businesses may be reducing, the administrative burden on EU officials is increasing. Such an approach could also pose significant risks to health and the environment where: (i) the risks involved are long-term and difficult to predict; and/or (ii) interested economic actors produce, fund or otherwise influence research with the specific intention of creating scientific uncertainty (as tobacco, chemical and other industries have all done[25,26,27]).

4. Facilitating corporate attempts to delay and block regulation

A mandatory requirement for policy decisions to be informed by IA provides stakeholders with a tool to challenge both proposed and existing legislation. This can and has been used to delay and weaken proposed EU regulation (see **Box 4**) and could be used to repeal enacted legislation. It can thus lead to avoidable harms being caused to populations and the environment.[28]

Box 4: How the chemicals industry employed IA to weaken EU legislation[29]

Underpinned by the precautionary principle, REACH (the Registration, Evaluation, Authorisation and Restriction of Chemical Substances) is potentially one of the EU's most important pieces of legislation. Intended to ensure that all chemicals would be tested for safety, it was originally designed to ensure companies (rather than regulators) were responsible for providing data to support safety claims. However, the chemical industry successfully diluted key aspects of the proposed regulation, including the requirement for mandatory substitution for some of the most hazardous chemicals, and there is evidence that IAs played a crucial role in this. In addition to employing its greater resources to dominate the European Commission's internet consultation, producing its own IAs emphasising the potential costs of REACH, the chemicals industry influenced the Commission's own IAs of REACH in several ways. DG Research commissioned an external consultancy firm to evaluate the impact of REACH on the competitiveness of the European chemicals industry. However, this consultancy firm had already produced an IA for the chemicals industry and it used the same parameters and methods of calculation for both studies, resulting in a significant over-estimation of the likely economic impact of REACH. Despite the fact this IA was effectively dismissed by the European Parliament, in the same year DG Enterprise and DG Environment signed a Memorandum of Understanding with the chemical industry, which led to the industry paying for two further IAs to be conducted by other consultancy firms and one by the Commission's Institute for Prospective Technological Studies, all three of which were incorporated by the Commission in their overall analysis of the likely impacts of REACH. Several non-governmental organisations were involved in monitoring this process but two withdrew, claiming that the study methods lacked transparency, were inconsistent and imbalanced, and placed undue focus on business impacts. Environmental campaign groups claim that the industry's efforts subsequently resulted in significantly weaker legislation than the Commission had originally proposed.[30,31]

Conclusions and Implications for policy

- BAT worked, often covertly and with other corporations, to promote a form of IA that would prioritise corporate interests, often at the expense of public health legislation. This approach to IA significantly influenced the EU's current integrated IA system.

- By working via third parties and member states, the extent of corporate interest in, and influence on, IA was remained hidden.

- There is an urgent need for the Commission and its staff to recognise the origins of and the potential pitfalls and dangers in its current approach to IA. It is essential to recognise that, whilst IAs can act as useful guides, they rarely provide certainty and are open to manipulation.

- The Commission should undertake a major review of IA which considers:
  (a) The administrative burden involved for officials, given that IAs are now required for all significant policy decisions and the number of IAs is increasing annually (impact assessments were produced for at least 122 European Commission proposals in 2008).
  (b) The need for health, social and environmental impacts of major policies to be adequately assessed and given equal status with economic impacts. This will require the development of appropriate infrastructures and data, particularly if such impacts are to be adequately costed across all member states;
  (c) The ways in which the current approach can favour corporate interests over others;
  (d) Given the resource differences between various types of organisation, it may also be necessary to ensure parties with fewer resources to track policy development (e.g. civil society organisations) are aware of and able to participate in IAs.

- Similarly, it is essential to ensure that all sectors are appropriately involved in any review, regardless of their financial ability to participate.

References:

1 European Commission (2009) Impact Assessment Guidelines SEC(2009) 92. Brussels: URL: http://ec.europa.eu/governance/impact/commission_guidelines/docs/iag_2009_en.pdf (accessed 17 Sep 2009).

2 Franz J, Kirkpatrick C (2007) Integrating Sustainable Development into European Policymaking: The Role of Impact Assessments. Journal of Environmental Assessment Policy and Management 9: 141-160.

3 Wilkinson D, Monkhouse C, Herodes M, Farmer A (2005) For Better or for Worse? The EU's 'Better Regulation' Agenda and the Environment. http://www.ieep.eu/publications/pdfs/2005/forbetterorforworse.pdf (accessed on 13 Jan 2009): Institute for European Environmental Policy.

4 Salay R, Lincoln P Health impact assessments in the European Union. The Lancet 372: 860-861.

5 Ståhl T (2009) Is Health Recognised in the EU's Policy Process? An analysis of the European Commission's impact assessments. European Journal of Public Health. Advance Access Published Online (http://eurpub.oxfordjournals.org/cgi/reprint/ckp082v1) on 23 June 2009.

6 Salay R, Lincoln P (2008) The European Union and Health Impact Assessments Are they an unrecognised statutory obligation? London: National Heart Forum.

7 European Communities (1997) Treaty of Amsterdam Amending the Treaty on European Union, the Treaties establishing the European Communities and Certain Related Acts. Brussels: Office for Official Publications of the European Communities and Europa: http://www.europarl.europa.eu/topics/treaty/pdf/amst-en.pdf (accessed on 07 Oct 2008).

8 Hervey T, McKee M, Gilmore A (Forthcoming) Public Health Policies. In: Mossialos E, Permanand G, Baeten R, Hervey T, editors. Health systems governance in Europe: The role of EU law and policy: Cambridge University Press.

9 BAT. (Undated). Shaping the Regulatory Environment: Advertising and Public Smoking. (Bates number(s): 322121140-322121143). Source: BAT. URL: http://bat.library.ucsf.edu//tid/xnz82a99 (accessed 23 May 2008).

10 Honour, H. (1996). Risk Assessment (Bates number(s): 800103062). Source: BAT. URL: http://legacy.library.ucsf.edu/tid/fjt14a99 (accessed 24 Jul 2008).

11 MacKenzie-Reid, D. (1995). Memo from Duncan MacKenzie-Reid to Keith Gretton enclosing paper on risk assessment. (Bates number(s): 800147230-800147236). Source: BAT. URL: http://bat.library.ucsf.edu//tid/ctt72a99 (accessed 12 Jul 2008).

12 Smith KE, Fooks G, Collin J, Weishaar H, Gilmore A (Under review) Manufacturing Better Regulation - Corporate Influence in the EU. Submitted to Regulation & Governance in October 2009.

13 Anonymous (1999) Fair Regulation Initiative: Campaign Group Presentation: 27 January 1999. (Bates number(s): 321332622-321332638). Source: BAT. URL: http://legacy.library.ucsf.edu/tid/zuy23a99 (accessed 30 Jul 2008).

14 Summers, M. (2000). Fair Regulation Campaign - Useful for EU Regulation and Regulatory Best Practice Discussions (Bates number(s): 322239554-322239555). Source: BAT. URL: http://bat.library.ucsf.edu//tid/ari23a99 (accessed 09 Jul 2008).

15 [BAT]. (1997b). Cost Benefit Analysis and Risk Assessment Working Group (Note of Meeting Oct 1997) (Bates number(s): 321573259-321573260). Source: BAT. URL: http://bat.library.ucsf.edu//tid/cgg63a99 (accessed 03 Jun 2008).

16 Ballantine, B. (1997). Conference: Evaluating Risk - A Balancing Act. (Bates number(s): 321573176-321573178). Source: BAT. UTL: http://bat.library.ucsf.edu//tid/cfg63a99 (accessed 04 Jun 2008).

17 Chalfen, S. P. (1996c). Note from regarding meeting at Brussels offices. (Bates number(s): 800102517-800102522). Source: BAT. URL:http://legacy.library.ucsf.edu/tid/hhf14a99 (accessed 01 Aug 2008).

18 Chalfen, S. P. (1996d). Note from Stuart P Chalfen to Philippe Bocken regarding risk assessment and cost benefit analysis. (Bates number(s): 700513775-700513779). Source: BAT. URL: http://bat.library.ucsf.edu//tid/vgj23a99 (accessed 02 Jun 2008).

19 EPC. (1998b). Forum on Risk: Brussels 12 March 1998. (Bates number(s): 321574226-321574232). Source: BAT. URL: http://legacy.library.ucsf.edu/tid/qhf61a99 (accessed 02 Aug 2008).

20 Crossick, S. (1997c). Risk Assessment. (Bates number(s): 321573196). Source: BAT. URL: http://bat.library.ucsf.edu//tid/igf61a99 (accessed 04 Jun 2008).

21 EPC. (1998a). Approval of Mission Statement and Prospectus. (Bates number(s): 321574237- 321574238). Source: BAT. URL: http://legacy.library.ucsf.edu/tid/ujg63a99 (accessed 01 Aug 2008).

22 Smith, K.E., Gilmore, A., Fooks, G., Collin, J. & Weishaar, H. (2009) Tobacco industry attempts to undermine Article 5.3 & the 'good governance' trap. Tobacco Control 18(6): 509-511.

23 Smith, K. E., Fooks, G., Collin, J., Weishaar, H. & Gilmore, A. (In press). Is the increasing policy use of Impact Assessment in Europe likely to undermine efforts to achieve healthy public policy? Journal of Epidemiology & Community Health.

24 Mandelkern Group on Better Regulation. Final Report. Brussels. URL: http://ec.europa.eu/governance/impact/docs/key_docs/mandelkern_report_en.pdf (accessed on 30th December 2008): Europa2001.

25 Brownell KD, Warner KE. The Perils of Ignoring History: Big Tobacco Played Dirty and Millions Died. How Similar Is Big Food? The Milbank Quarterly 2009;87[1]:259-94.

26 Freudenberg N, Galea S. The impact of corporate practices on health: implications for health policy. Journal of Public Health Policy 2008;29[1]:86-104.

27 Wiist WH. Public health and the anticorporate movement: rationale and recommendations. American Journal of Public Health 2006;96[8]:1370-5.

28 European Environment Agency. Late Lessons from Early Warnings: The Precautionary Principle 1896-2000. Copenhagen: European Environment Agency2001.

29 Smith, K.E., Fooks, G., Collin, J., Weishaar, H., Mandal, S. and Gilmore, A. (2010) "Working the System"?British American Tobacco's Influence on the European Union Treaty and Its Implications for Policy: An Analysis of Internal Tobacco Industry Documents. PLoS Med 7(1): http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.1000202.

30 Contiero M. Toxic Lobby. How the Chemicals Industry is Trying to Kill REACH. Brussels. Also available at http://www.greenpeace.org/raw/content/international/press/reports/toxic-lobby-how-the-chemical.pdf (accessed on 13th January 2008) Greenpeace International2006.

31 International Chemical Secretariat. Cry Wolf - Predicted Costs by Industry in the Face of New Regulation. Göteborg & online at: http://assets.panda.org/downloads/crywolf0404b.pdf (accessed on 10th April 2009): The International Chemical Secretariat2004.

Research Briefing 2: The Risks in Risk Assessment

Research Briefing 2: The Risks in Risk Assessment

Executive Summary

In recent years, the Commission's guidelines on impact assessment have paid increasing attention to risk assessment.[1] Assessing the potential risks in advance of proposals for policy action seems sensible. However, recent research demonstrates that large corporations whose products are potentially damaging to health and the environment, including the tobacco and chemical industries, have played a key role in promoting risk assessment in the EU. This is because senior managers at some of the companies involved believed a particular approach to risk assessment could work in their favour by making it more difficult for policymakers to justify regulatory interventions that, whilst protecting public health, might damage their profits. This research demonstrates that:

- From 1995 onwards, senior managers at British American Tobacco (BAT, the world's second largest transnational tobacco company) believed a requirement for structured risk assessment could be used to prevent legislation restricting smoking in public places. Consequently, BAT began working to try to ensure structured risk assessment of all EU policies became obligatory.
- Having been advised that risk assessment was not on the EU agenda and that any campaign connected to the tobacco industry was unlikely to succeed, BAT recruited other business interests to a long-term lobbying strategy, which involved promoting risk assessment as part of the broader set of business friendly reforms, now known as Better Regulation.
- The European Policy Centre has played a key part in this campaign, obscuring the commercial interests involved.
- This campaign has been extremely successful and is ongoing, helping create a legislative environment in the EU which is at risk of consistently prioritising business interests over others, including the environment and health, thus putting the health of EU citizens at risk.

This briefing explains what risk assessment is, what BAT and other businesses hoped to achieve by promoting it and how this campaign functioned. It then outlines the potential dangers posed in relation to current, ongoing efforts to redefine policymakers' perceptions and understandings of risk, before outlining the key conclusions and implications for policy.

What is risk assessment?

Risk assessment is a means of assessing the potential risk posed by a particular hazard. In a policy context, risk assessment is designed to help inform decisions about whether legislative intervention is required to help manage a particular risk. It is thus usually undertaken early in the policymaking process, in advance (or at a preliminary stage) of impact assessment.

Why have British American Tobacco and other large corporations been promoting Risk Assessment in the EU?

From 1995 onwards, senior managers at BAT wanted to lobby for what they termed 'structured risk assessment' in the EU because they believed it could be used to prevent the introduction of public smoking restrictions, which were seen to be a growing threat in Europe at that time (see **Box 1**).[2] BAT had learnt that risk assessment could be used in this way from the American tobacco company, Philip Morris, which had successfully redefined risk assessment in the USA so that it could be used to challenge, rather than support, the classification of Environmental Tobacco Smoke (ETS) as a threat to health.[3] However, BAT was advised that the European Commission was not, at that time, interested in risk assessment,[4,5] so it began exploring alternative ways of promoting risk assessment in the EU. This involved linking risk assessment with broader regulatory changes, particularly business impact assessment, which later became collectively known as Better Regulation.

Box 1: Excerpt from an internal BAT document,[6] dated 1995, explaining that senior managers at the company believed risk assessment could help the tobacco industry challenge claims about the health impacts of environmental tobacco smoke (ETS):

Rationale

It is believed that if a structured risk assessment that included proper rules for the assessment of epidemiologic and animal data were applied to the existing ETS science, then it would be apparent that ETS has not been proven to be a cause of disease in non-smokers. A legislated demand for structured risk assessment would then remove the possibility of introducing public smoking restrictions that are based on risk claims.

It is important to note that by this stage the industry was well aware of the negative health impacts of Environmental Tobacco Smoke but was simultaneously trying to influence the evidence base on the issue.[6]

How did BAT and other large corporations work to promote risk assessment?

BAT was advised that it might be able to promote risk assessment by linking it to the European Commission's commitment to undertaking Business Impact Assessment (BIA)[7] which had been flagged as a priority for 1996. This, it was suggested, could be used to press for *'More detailed guidance on the preparation of business impact assessments, perhaps including elements of structured risk assessment'.*[7] At the same time, BAT was also being advised by external consultants that BIA could be used more generally as a means of increasing business influence over policy decisions. Hence, for the first decade of the campaign, from 1995 onwards, efforts were largely focused upon promoting the need for BIA (see Research Briefing 1) and for better consultation with business actors (see Research Briefing 3), despite the underlying intention to eventually secure a particular form of risk assessment. Nevertheless, promotional material frequently suggested risk assessment was a necessary part of BIA, paving the way for the campaign to focus on risk related matters at a later stage.[2] Risk assessment is now included in the Commission's guidelines on impact assessment.[1]

Re-framing policy perceptions of, and responses to, risk

Now that a requirement for a business orientated form of IA and consultation with 'interested parties' have both been achieved (see Research Briefings 1 and 3), the campaign has evolved to focus more clearly on redefining policymakers' approaches to risk, which was BAT's original aim.[2] In 2006-2007, the coalition of companies involved in the European Policy Centre's Risk Assessment Forum established themselves as an independent group called the European Risk Forum.[2] This group, which describes itself as a 'think tank' despite solely representing corporate interests, is now actively promoting the idea that the European Commission needs to adopt a more structured approach to risk assessment and risk management.[8] Recent analyses suggest efforts to redefine policymakers' understandings of, and responses to, risks, including those aimed at limiting the use of the Precautionary Principle (see **Box 2**), have met with some success in the EU[9] and UK[10] (which BAT identified as a potential 'model' for promoting risk assessment in the EU.)[2]

Box 2: Corporate interests and the Precautionary Principle

The *Precautionary Principle* states that, where there are reasonable grounds to believe that a given hazard would, if it occurred, result in severe or irreversible damage to the public's health or the environment, policymakers should act to prevent that risk, even where there is not yet a scientific consensus about its likely occurrence and/or impact. The companies involved in the campaign described above were concerned about how the Precautionary Principle was being interpreted and employed by policymakers in the EU, fearing it may lead to legislation affecting their economic interests. Hence, as part of their collective efforts to promote a form of risk assessment that would work to businesses' advantage, they attempted to influence how this Principle was understood and applied in the EU.

Future Dangers

The lobbying campaign uncovered by this research has already substantially altered the way in which policy decisions in the EU are made and there is potential for this influence to increase further if policymakers do not become more alert to what is happening. The campaign appears to be ongoing and is currently focusing on influencing policy perceptions of, and responses to, risk, which was the original driver for BAT's campaign. This raises the possibility that large corporations which profit from the manufacture and sale of some of the most toxic products in Europe could further influence the rules governing how the associated risks are handled.

Conclusions and Implications for policy

- Having observed developments in the USA, BAT believed that a mandatory requirement for a particular form of risk assessment in the EU could help prevent public health policies that it feared would affect its commercial interests.
- Aware that a campaign focusing on issues of risk that was known to be connected to the tobacco industry was unlikely to succeed, BAT conducted its campaign through third party organisations (particularly the well-respected think tank, the European Policy Centre) and with corporations in other sectors.
- Having been advised, in 1996, that risk assessment was not on the Commission's agenda, BAT and its allies worked first to promote a form of BIA, with the intention of using this to promote the need for risk assessment. Not only is a form of BIA now

mandatory for all EU policy decisions (see Research Briefing 1) but the current guidelines now include a section on risk assessment.

- The Commission needs to fundamentally review its approach to risk assessment in light of these findings and ensure that its policy processes are able to adequately protect health and the environment and are not biased in favour of corporate interests.
- In the meantime, policymakers must be alert to the possible interests involved in efforts to promote a new approach to assessing and managing risk in the EU.
- When judging the validity of such efforts or claims about risk, particularly those involving external stakeholders, officials should establish which interests are involved (see Research Briefing 3).

References

1 European Commission (2009) Impact Assessment Guidelines SEC(2009) 92. Brussels: URL: http://ec.europa.eu/governance/impact/commission_guidelines/docs/iag_2009_en.pdf (accessed 17 Sep 2009).

2 Smith KE, Fooks G, Collin J, Weishaar H, Gilmore A (Under review) Manufacturing Better Regulation - Corporate Influence in the EU. Submitted to Regulation & Governance in October 2009.

3 Hirschhorn N, Bialous SA (2001) Second hand smoke and risk assessment: what was in it for the tobacco industry? Tobacco Control 10: 375-382.

4 Gretton, K. (1996). Risk Assessment Progress (Bates number(s): 800147892-800147900). Source: BAT. URL: http://bat.library.ucsf.edu//tid/cvb53a99 (accessed 03 Jun 2008).

5 Crossick, S. (1996). Risk Assessment Project. (Bates number(s): 700513813-700513841). Source: BAT. URL: http://bat.library.ucsf.edu//tid/ehj23a99 (accessed 02 Jun 2008).

6 Ong, E. K., & Glantz, S. A. (2000). Tobacco industry efforts subverting International Agency for Research on Cancer's second-hand smoke study. *The Lancet, 355*(9211), 1253-1259.

7 Covington & Burling. (1996). EC Risk Assessment Proposal. (Bates number(s): 800103063-800103065). Source: BAT. URL: http://bat.library.ucsf.edu//tid/hjt14a99 (accessed 12 Jul 2008).

8 European Risk Forum. (2008c). *Policy Brief 04: Judicial Review and Risk Management at EU-Level.* Brussels and online: http://www.euportal2.be/images/erf%20policy%20brief%20judicial%20review%20001.pdf (accessed 09 Sep 2009): European Risk Forum.

9 Löfstedt, R. E. (2004). The Swing of the Regulatory Pendulum in Europe: From Precautionary Principle to (Regulatory) Impact Analysis. *The Journal of Risk and Uncertainty, 28*(3), 237-260.

10 Dodds, A. (2006). The Core Executive's Approach to Regulation: From 'Better Regulation' to 'Risk-Tolerant Deregulation'. *Social Policy & Administration, 40*(5), 526-542.

Research Briefing 3: Stakeholder Consultation, Regulatory Capture and the 'Good Governance' Trap

Research Briefing 3: Stakeholder Consultation, Regulatory Capture and the 'Good Governance' Trap

Executive Summary

Over the past decade, the European Commission has been making concerted efforts to increase the transparency of the European policymaking process as part of its 'Good Governance' agenda. Such reforms are widely perceived to be a means of improving EU legislation by protecting it from inappropriate and often covert business lobbying. However, recent research demonstrates that large corporations have been using commitments to transparency and good governance to increase their ability to influence EU policy. This research demonstrates that:

- As part of its campaign to promote a series of regulatory reforms in the EU, British American Tobacco (BAT) worked with other large corporations to promote the idea that a lack of consultation with stakeholders (particularly business interests) was widely deemed to be problematic in the EU and that increased consultation formed an essential element of the impact assessment process (see Research Briefing 1).
- These claims fed directly into calls for the Commission to produce minimum standards on consultation with stakeholders and interested parties.
- In 2002, the Commission produced precisely such standards and they took effect from January 2003.
- Having played a role in promoting these standards, tobacco companies are now employing them to challenge policy commitments that threaten their interests.

This briefing summarises how BAT and other large corporations worked (in a paradoxically non-transparent manner) to promote the idea that consulting corporations about proposed legislation at an early stage would help improve transparency in the EU. It then explains how tobacco companies are employing these same policy commitments to undermine a World Health Organisation global public health treaty on tobacco control that the EU has signed and ratified. It concludes by outlining the key conclusions and implications for policy.

Why is the EU under pressure to increase transparency and what does this involve?

In 1996, a European Commission communication mentioned transparency amongst a number of other proposals for improving the legislative process in the EU.[1] However, this did not appear to stimulate any significant action.[2] In contrast, a major scandal at the Commission in 1999, in which 20 Commissioners resigned over allegations of nepotism and corruption,[3] led to a far more significant focus on transparency. As part of efforts to increase transparency and improve its ethical conduct, the Commission issued a communication entitled *'Towards a reinforced culture of consultation and dialogue - General principles and minimum standards for consultation of interested parties by the Commission'* in 2002.[4] In 2005-2006, under the leadership of Commission President José Manuel Barroso and Commissioner for Administrative Affairs, Siim Kallas, the Commission launched the European Transparency Initiative.[2] This includes proposals relating to aspects of interest group activity and ideas about improving ethical standards for EU officials.

This briefing focuses specifically on the governance of interest group activity, an issue over which the Commission has been facing a great deal of pressure as there is a perception that corporate lobbyists have been successfully increasing their influence on the European political agenda in recent years.[2] One of the biggest sources of such pressure has been the Alliance for Lobbying Transparency and Ethics Regulation (ALTER-EU), a coalition of over 160 civil society and other organizations. Responding to such pressure, in 2008, the Commission launched a Register of Interest Representatives, with the stated aim of *'let[ting] citizens know which general or specific interests are influencing the decision-making process of the European Institutions and the resources mobilized to that end.'*[5] However, the voluntary nature of the register has attracted criticism,[6] and the issue of transparency in the EU therefore remains hotly debated.

Who do commitments to improving transparency in the EU benefit?

Many commentators believe an increase in transparency in the EU will benefit civil society organisations and the wider public by protecting EU policy decisions from excessive behind-the-scenes lobbying undertaken by well-resourced business interests.[6] However, as early as 1996, BAT was advised that commitments to increased transparency could be used '*to press for more elaborate consultation*' of business interests.[7] In pursuing a package of regulatory reforms that it believed would help protect its European interests (see Research Briefings 1 and 2), BAT, and other corporations it was working with, employed the concept of 'transparency' and

'good governance' as a means of promoting the need for consultation with affected parties at an early stage in the policy process (see **Box 1**).[8] These proposals were overtly linked with calls for a business orientated form of impact assessment (see Research Briefing 1).

Box 1: How BAT and other large corporations exploited EU commitments to transparency and good governance to further their own interests

Internal company documents, released as a result of litigation, show that from 1996 onwards, BAT established a coalition of companies and worked with a widely respected think tank, the European Policy Centre (EPC), to ensure that corporations would be included in European policy discussions and formally consulted early in policymaking processes.[8] These efforts included the publication by EPC, in September 2001, of an officially commissioned paper on business impact assessment. This paper was based on work by the EPC Risk Forum which was chaired by BAT's head of science and regulation. It argues that better consultation is needed during policy development and recommends that the Commission should establish *'mandatory standards for consultation'* which would involve stakeholders at a very early stage in the policymaking process. This paper is drawn on heavily in a Business Impact Assessment Pilot Report subsequently produced by the Commission, whose recommendation that *'[k]ey minimum standards for consultation should be implemented'* appears to have been based directly on the EPC paper. In December 2002, precisely such Minimum Standards for consultation were published by the European Commission (taking effect on 1st January 2003). As might be expected, these standards stress the need for early consultation with interested parties and, according to interviews the researchers undertook in September 2008, have been interpreted by Commission staff (even those in the Directorate General for Health and Consumers) as requiring in-person consultation with the tobacco and other industries.

What's the problem with consulting corporations about proposals for EU legislation that may affect their interests?

Where consultation works to widen participation in the early stages of policy formation, this can improve the democracy and transparency of formal decision-making. However, requiring public officials to consult businesses which have a well-documented history of manipulating policy outcomes through covert means[9,10,11] may undermine policies designed to safeguard public health, particularly if other, less well-resourced stakeholders are (due to resource limitations) either unaware of or unable to fully participate in consultation processes. For example, an exploration of the development of legislation relating to the regulation of chemicals in Europe (see Box 4 in Research Briefing 1), suggests inclusive approaches to consultation can privilege business interests when the relevant debates are too technical to be understood by most other stakeholders.[12]

Is the tobacco industry a special case?

The way in which the tobacco industry works is unlikely to differ significantly from other corporations[9,10,11] and there is now substantial evidence that corporations have acted collectively to influence EU policy processes.[13] However, as a result of litigation which forced the tobacco industry to make its internal documents public, we now know far more about tobacco than other industries.[14] This knowledge has, in turn, prompted efforts to reduce the tobacco industry's influence on policy via the Framework Convention on Tobacco Control (FCTC),[15] the first global public health treaty to be developed by the World Health Organisation (WHO) which has now been ratified by 168 countries/regions, including the EU. In recognition of the now well documented, systematic and often covert tobacco industry efforts to undermine tobacco control policy,[16,17] Article 5.3 of the FCTC specifically requires that, *'in setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.'* This means **all** EU officials need to be particularly careful about consulting the tobacco industry or its representatives.[8] Commission officials in directorates other than Health and Consumers need to be especially aware of these issues as previous evidence indicates that the industry will specifically seek to exert influence via policymakers without responsibility for health issues.[18,19]

How are commitments to 'transparency', 'good governance' and 'better regulation' helping the tobacco industry?

In the EU and the UK, the strategy being employed by major tobacco companies (both prior and subsequently to the agreement of the guidelines for Article 5.3 of the FCTC) is to claim that Article 5.3 contravenes existing official standards on consultation because it requires complete exclusion of the tobacco industry from policy discussions (in fact, it merely requires that consultation should be limited to that which is strictly necessary and should be transparent and accountable).[8] Such claims are frequently framed within broader policy commitments to 'better regulation' or 'good governance', as **Box 2** illustrates.[8]

Who lobbies on behalf of the tobacco industry?

The tobacco industry employs many different kinds of organisations and individuals to lobby on its behalf, including law firms, public relations firms, consultancy firms, non-governmental organisations (e.g. smokers' rights groups), campaign groups and even organisations and individuals who might be expected to be more independent, such as academics and think tanks.[13,20,21] Where a convenient group does not already exist, the industry may set one up to act on its behalf.[20] Furthermore, if the industry has been successful in lobbying particular Member States, then Member State representatives may also (inadvertently or otherwise) be lobbying on the industry's behalf.[13]

How can policymakers tell if an organisation (or individual) is lobbying on behalf of the tobacco industry?

In a policy system as complex as that in Europe, it can be extremely difficult to tell whether an individual/organisation is lobbying on behalf of the tobacco industry or any other specific interests. Whilst recent revisions to guidance on consulting interested parties encourages lobbyists to disclose their interests and policymakers to make efforts to increase their awareness of the interests involved, such requirements are not mandatory and there are no significant penalties for those who do not follow this guidance.[6]

Box 2: Extracts from tobacco industry letters and other recent lobbying materials attempting to undermine the WHO Framework Convention on Tobacco Control (FCTC)

Company/organisation, context & date	Claim in relation to Article 5.3 / proposals to limit tobacco industry interference within policymaking (emphases added)
Prior to Article 5.3 Guidelines being agreed in Durban in November 2008	
Japan Tobacco International to the European Affairs Office, 12th June 2008	'The benefits of stakeholder consultation have been widely recognized both at national and international levels and JTI, therefore, believes that the Parties [to the FCTC] should **reject any suggestion that the tobacco industry should be excluded, whether expressly or in fact, from the regulatory process.** Such an approach would be contrary both to accepted international practices, of which stakeholder consultation forms an essential part, and national constitutional principles and law. […] **The protection of the legislative process should be founded on internationally accepted principles of Better Regulation**…'[22]
BusinessEurope (which BAT has close connections with[b]) to José-Manuel Barroso (President of the European Commission), 29th August 2008	'BusinessEurope has always been a **strong supporter of the Commission's policy to try to achieve Better Regulation** for growth and jobs in the EU. […] **[P]roper consultation of all affected stakeholders carried out in accordance with the Commission's general principles and minimum standards is crucial** for getting an idea about the cost-effectiveness of legislation. For this reason, we are seriously worried about developments in the framework of the ongoing negotiations within the World Health Organisation on draft guidelines that will implement Article 5.3 of the WHO Framework Convention on Tobacco Control (FCTC) where one of the issues is **the attempt by national and EU health authorities to exclude the tobacco industry from being consulted on policy and legislation.'** [23]
BAT response to the UK Department of Health discussion document 'Consultation on the future of tobacco control', 5th Sept 2008	'[W]e are concerned that the draft Guidelines pursuant to Article 5.3 of the Framework Convention on Tobacco Control (FCTC) could result in less than full and proper consultation with the tobacco industry. Such a proposal would be **inconsistent, not only with UK Government policy but with the European Commission's commitment to open consultation.** […] We request that the UK Government promotes in international fora, such as discussions relating to the development of the FCTC Guidelines, **the principles of better regulation to which it is committed, to ensure that all relevant stakeholders, including the tobacco industry, are properly consulted and listened to,** now and in the future, on issues affecting their businesses.'[24]
Subsequently to Article 5.3 Guidelines being agreed in Durban in November 2008	
Imperial Tobacco letter to the House of Lords in the UK, 28th April 2009	After explaining that an amendment has been submitted to a Health Bill, 'to establish a review of the government's policies on engagement with the tobacco industry in line with Article 5.3,' Imperial Tobacco's letter claims that: **'This amendment is completely opposed to the general principles of Better Regulation that were documented in 2006** […] Governments must acknowledge that to be effective, **consultation must start as early as possible.** Interested parties should therefore be involved in the development of a policy at an early stage.'[25]

Conclusions and Implications for policy

- Whilst EU policy commitments to transparency are intended to ensure that the EU policymaking process is as fair and democratic as possible, large corporations have been employing this agenda to secure their inclusion in policy discussions at an early stage, believing this is likely to increase their ability to influence policy outcomes.
- The research indicates that the campaign to promote the idea that consultation with businesses forms a central part of the transparency agenda has been successful and that this success was partly due to the fact the campaign was itself undertaken in a largely non-transparent manner, employing the use of third party organisations (notably a prominent think tank, the European Policy Centre).

Generic Implications:

- EU officials need to be continuously alert to the fact that the lobbying is frequently undertaken in a covert manner. Current policy initiatives intended to improve transparency in the EU, including the Commission's Register of Interests, do not yet appear to be sufficient to ensure that interested parties are fully transparent in their lobbying techniques.
- Particular care may need to be taken with think tanks, given their diverse client base and clear evidence that even well respected think tanks have acted to promote particular corporate interests.
- In light of what is known about the previous behaviour of some corporate actors (such as the tobacco industry), the Commission ought to recognise that consultation with 'interested parties' is not necessarily in the public interest or synonymous with 'good governance'.
- A commitment to consultation does not necessarily require in-person consultation. Where there are concerns about the potential for an 'interested party' to manipulate consultation processes, it may be more appropriate for all consultation to be conducted in writing (for example, via on-line systems) so that it can be openly monitored.

Implications specifically in relation to the tobacco industry:

- The principle that consultation with 'interested parties' is not always in the public's interest is enshrined in Article 5.3 of the WHO's FCTC, which the EU has signed and ratified. In order to ensure that the Commission's commitments to achieving transparency succeed and that the Commission does not break its legal obligation to the FCTC, it urgently needs to explore the implications of Article 5.3 for its current approach to consulting 'interested parties' and ensure that all Directorates review their guidance on interacting with the tobacco industry.

References

1 Commission of the European Communities (1996) Better Lawmaking - Commission Report to the European Council on the application of the subsidiarity and proportionality principles, on simplification and on consolidation. Brussels. URL: http://aei.pitt.edu/924/01/subsidiarity_CSE_96_7.pdf

2 Cini, M. (2008). European Commission Reform and the Origins of the European Transparency Initiative. *Journal of European Public Policy* 15(5), 743-760.

3 CNN. (1999). *EU in turmoil after executive commission resigns.* http://www.cnn.com/WORLD/europe/9903/16/eu.commission.01/ (accessed 06 Oct 2008): CNN.

4 Commission of the European Communities. (2002). Towards a reinforced culture of consultation and dialogue - General principles and minimum standards for consultation of interested parties by the Commission (COM(2002) 704 final): http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0704:FIN:EN:PDF (accessed 26 Aug 2008).

5 Commission of the European Communities (2009) Register of Interest representatives of the European Commission and List of Lobbyists accredited to the European Parliament. Europa. URL: http://europa.eu/lobbyists/interest_representative_registers/index_en.html (accessed 07 Oct 2009)

6 ALTER-EU (Alliance for Lobbying Transparency and Ethics Regulation) (2006) About ALTER-EU. URL: http://www.alter-eu.org/en/system/files/files/alter-eu/publications/COE_Broschure_07-WEB.pdf (accessed 10 Sep 09)

7 Covington & Burling. (1996). EC Risk Assessment Proposal. (Bates number(s): 800103063-800103065). Source: BAT. URL: http://bat.library.ucsf.edu//tid/hjt14a99 (accessed 12 Jul 2008).

8 Smith, K.E., Gilmore, A., Fooks, G., Collin, J. & Weishaar, H. (2009) Tobacco industry attempts to undermine Article 5.3 & the 'good governance' trap. *Tobacco Control* 18(6): 509-511.

9 Brownell KD, Warner KE. The Perils of Ignoring History: Big Tobacco Played Dirty and Millions Died. How Similar Is Big Food? *The Milbank Quarterly* 2009;87[1]:259-94.

10 Freudenberg N, Galea S. The impact of corporate practices on health: implications for health policy. *Journal of Public Health Policy* 2008;29[1]:86-104.

11 Wiist WH. Public health and the anticorporate movement: rationale and recommendations. *American Journal of Public Health* 2006;96[8]:1370-5.

12 Pesendorfer D. EU environmental policy under pressure: Chemicals policy change between antagonistic goals? *Environmental Politics* 2006;15[1]:95 - 114.

13 Smith, K.E., Fooks, G., Collin, J., Weishaar, H., Mandal, S. and Gilmore, A. (2010) "Working the System"?British American Tobacco's Influence on the European Union Treaty and Its Implications for Policy: An Analysis of Internal Tobacco Industry Documents. PLoS Med 7(1): e1000202. doi:10.1371/journal.pmed.1000202.

14 Collin, J., Lee, K., & Gilmore, A. B. (2004). Unlocking the corporate documents of British American Tobacco: an invaluable global resource needs radically improved access. Lancet *(British edition)*, 363(9423), 1746-1747.

b BusinessEurope's members are European Member State national federations of industries. The UK federation is the Confederation of British Industry (CBI). BAT is a member of the CBI and has a history of working closely with it. The current President of the CBI is Martin Broughton, who was Chair of BAT from 1998-2004.

15 WHO (World Health Organization). Framework Convention on Tobacco Control. http://www.who.int/tobacco/framework/WHO_FCTC_english.pdf (accessed at 19.11 on 16th August 2008); 2003.

16 World Health Organisation. Tobacco Industry Interference with Tobacco Control. 2008. http://www.who.int/tobacco/resources/publications/9789241597340.pdf (accessed on 20 Jun 2009).

17 Neuman M, Bitton A, Glantz S (2002) Tobacco industry strategies for influencing European Community tobacco advertising legislation. The Lancet 359: 1323-1330.

18 Duina, F., & Kurzer, P. (2004). Smoke in your eyes: the struggle over tobacco control in the European Union. *Journal of European Public Policy,* 11(1), 57-77.

19 Cairney, P. (2007). A 'Multiple Lenses' Approach to Policy Change: The Case of Tobacco Policy in the UK. *British Politics,* 2(1), 45-68.

20 Ong, E. K., & Glantz, S. A. (2001). Constructing 'sound science': tobacco lawyers, and public relations firms. *American Journal of Public Health* 91(11), 1749-1757.

21 Grüning T, Gilmore AB, McKee M. Tobacco Industry Influence on Science and Scientists in Germany. *American Journal of Public Health* 2005;96:20-32.

22 Dorzia, P. (2008) Letter from JTI (Japan Tobacco Industry) to the European Affairs Office, dated 12th June 2008, copied to Health Attachés of all the Member States and the European Commission.

23 De Buck P. Letter from Business Europe to Jose Manuel Barroso dated 29th August 2008.

24 British American Tobacco (2008) British American Tobacco response to the Department of Health discussion document 'Consultation on the future of tobacco control, May 2008': http://www.bat.com/group/sites/uk__3mnfen.nsf/vwPagesWebLive/DO7J7CSX/$FILE/medMD7J7CUJ.pdf?openelement (accessed on 18 June 2009)

25 Pramanik, A. (2009) (Imperial Tobacco) Letter from Imperial Tobacco to the House of Lords, dated 28th April 2009. Bristol.

Acknowledgement

This report is based on work conducted by the University of Bath and University of Edinburgh. Dr Anna Gilmore and Dr Jeff Colin were the principal investigators, Dr Katherine Smith was the lead researcher and others involved were Dr Gary Fooks, Heide Weishaar and Dr Sema Mandal.

Cathy Flower provided valuable administrative support. The report was prepared by Dr Smith, Dr Gilmore and Dr Fooks and is based on the following research, which has been published in (or is currently under review at) peer reviewed journals:

- Smith, K.E., Fooks, G., Collin, J., Weishaar, H., Mandal, S. and Gilmore, A. (2010) "Working the System"?British American Tobacco's Influence on the European Union Treaty and Its Implications for Policy: An Analysis of Internal Tobacco Industry Documents. PLoS Med 7(1): http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.1000202

- Smith, K.E., Gilmore, A., Fooks, G., Collin, J. & Weishaar, H. (2009) Tobacco industry attempts to undermine Article 5.3 & the 'good governance' trap. Tobacco Control 18(6): 509-511.

- Smith, K. E., Fooks, G., Collin, J., Weishaar, H. & Gilmore, A. (In press). Is the increasing policy use of Impact Assessment in Europe likely to undermine efforts to achieve healthy public policy? Journal of Epidemiology & Community Health.

- Smith KE, Fooks G, Collin J, Weishaar H, Gilmore A (under review) Manufacturing Better Regulation - Corporate Influence in the EU. Submitted to Regulation & Governance in October 2009.

Funding

'This work was supported by the Smoke Free Partnership (SFP) through a CR-UK grant. CR-UK is one of the SFP partners (www.cancerresearchuk.org <www.cancerresearchuk.org>), the others being the European Respiratory Society (www.ersnet.org <www.ersnet.org>), the Institut National du Cancer (www.e-cancer.fr <www.e-cancer.fr>) and the European Heart Network (www.ehn.org <www.ehn.org>). Anna Gilmore is supported by a Health Foundation Clinician Scientist Award. The funders had no influence on the research design, data collection, data interpretation or the peer-reviewed research publications.

Design: inextremis.be