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**Title: Political controversy, issue salience and E-cigarette regulation in
Europe: A comparative study of policy debates in Germany and England**

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Abstract

Electronic cigarettes posed a regulatory challenge to governments seeking to balance the potential health benefits for existing smokers against the risks to wider public health. This comparative paper aims to explain the presence and absence of controversy about e-cigarette regulation in England and Germany, respectively. It identifies three sets of factors that help explain why e-cigarettes regulation became highly controversial in England, while in Germany this debate has been almost entirely absent. These factors relate to (1) differences in the perceived salience of e-cigarettes resulting from existing tobacco control measures, prevalence of e-cigarette use, the presence of the tobacco industry, and the role of public health community in public debate; (2) differences in institutional context and pathways of decision-making; and (3) differences in approaches to legitimise policy decisions through science and the judiciary. The paper highlights the complex interplay of political, institutional and cultural factors in explaining differences in regulatory decision-making.

Keywords

Comparative public policy analysis; evidence-based policy; public health; tobacco control

Introduction

As a new and initially unregulated technology, electronic cigarettes (e-cigarettes) posed a regulatory challenge to governments seeking to balance the potential health benefits for existing smokers against the risks to wider public health. In England, the process of developing e-cigarette regulation led to considerable controversy among public health researchers, advocates and policy-makers, while in Germany the same process did not generate the same degree of contestation. This difference is even more striking since both countries introduced the same regulatory measures in addition to implementing the European (EU) Tobacco Product Directive (TPD) that both countries had agreed to transpose by May 2016.

The paper argues that there are three sets of factors that can help explain the difference in the degree of policy controversy between both countries: The first set of factors relates to the prominence given to e-cigarettes by public health advocates and policy-makers resulting from existing tobacco control policies, their effects on smoking rates, the development of the tobacco market and incentives on consumers and tobacco firms to switch to e-cigarettes. The second set of factors includes the institutional context of public health policy-making that determines the pathways of decision-making and the roles of the policy actors involved. A third set of factors relate to differences in policy styles shaping public health decisions resulting in preferences for legitimising such decisions. To explore these factors, the paper draws on political science, policy analysis, public health and tobacco control literature.

This paper aims to explain the difference in the degree of policy controversy in England and Germany associated with the regulation of e-cigarettes. It uses a comparative case study analysis using interviews with key informants and relevant documents. It contributes an empirical analysis to our understanding of the factors informing the differences in policy controversy between countries. It also aims to contribute to the body of theory that conceptualises the interplay of political, institutional and cultural factors in explaining differences in policy discourse.

Analytical framework

The first set of factors relates to the difference in existing tobacco control measures and their effects on smoking rates and the market for e-cigarettes that influence the salience of the issue to policy actors. The paper argues that the success of existing tobacco control measures, resulting in reduced smoking rates, has shaped the demand for e-cigarettes, which, in addition to concerns about the influence of the tobacco industry on consumer behaviour, has made e-cigarette policy an issue of

high stakes for tobacco control and public health advocates (José, 2015; McKee et al., 2014; Watson and Forshaw, 2015). In a recent paper, Van de Graaf and colleagues demonstrate that public concern about ‘fracking’ is a key explanator for differences in decisions relating to shale gas regulation in Europe (Van de Graaf et al., 2017). Such public concern can also increase the demands on policy-makers to justify their decisions more explicitly, for example by reference to supporting scientific evidence (Oppermann and Viehring, 2008; Majone, 1989). The salience of the issue of e-cigarette policy in England could then explain why the policy required substantial legitimation and more so than in Germany where the issue was given less prominence by policy-makers and the public health community.

The second set of factors relates to the institutional pathways that shaped how the regulatory processes unfolded and which policy actors contributed to debates about regulating e-cigarettes. There is a substantial comparative literature that examines how differences in institutional structures influence policy choices (Steinmo et al., 1992; Thelen, 1999; Béland, 2016). Amongst liberal democracies, the UK and Germany follow contrasting constitutional models with the UK being a unitary constitutional monarchy and Germany being a federal republic (Colomer, 2006). Following this institutional logic, Germany is portrayed as a ‘semi-sovereign state’ (Katzenstein, 1987) in which power is highly defused and policy-making requires agreement from a largely number of institutional veto players that allow only for slow incremental policy change while producing a fair amount of institutional inertia. In the UK, in contrast, a ‘winner-take-all’ majoritarian system tends to concentrate power in the executive enabling rapid and sometimes drastic policy change (Tsibelis, 2008; Katzenstein, 2005). This may not be so straightforward given the ongoing process of devolution and the changing nature of state authority in Britain since the late. Nonetheless, the executive still has substantial decision-making power. As responsibility for public health policy has been devolved to its constituent jurisdictions and this paper focuses on England as the comparator country, rather than the UK as a whole, although some of the policy (e.g. the TPD) relate to the UK as the nation state rather than to England only.

In terms of health policy, Tuohy (1999) demonstrated that differences in institutional arrangements can produce idiosyncratic patterns of policy reform, with England being more likely to produce large-scale health reforms than countries in which power is more diffused. While it seems obvious that these institutional differences also result in different pathways of adapting EU legislation, there is debate about the extent to which the number of veto players influences the speed and completeness of adaptation (Haverland, 2002; Bailey, 2002). Such observed institutional difference highlight the role of policy actors in policy development and implementation, both as ‘veto players’ with the system and as commentators, critics and advocates outside the decision-making process.

A third set of factors analysed in the paper involves differences in policy styles and strategies of legitimation directly relating to public health. There is a dearth of comparative analysis of approaches to policy legitimation in different countries. Knill and Lenschow (1998) attest Germany a high degree of 'legalism' (i.e. reliance on procedures defined in law) and especially the "binding of the administration to the law (following the principle of the *Rechtsstaat*)" which they say "traditionally serves as a substitute for democratic representation". From this perspective, legitimacy of policy decisions is derived from compliance with the law and with legal administrative processes (Schmidt, 2005). This is juxtaposed with administrative approaches to implementing policy in the UK, which emphasises flexibility and administrative discretion and an outcome focused regulatory style, which is less reliant on existing administrative practice (Knill and Lenschow, 1998). Landfried (1992) warned that, in Germany, the reliance on courts, especially the Constitutional Court, in policy-making has often led to a reduction in policy options, suggesting that this is to the detriment of policy outcomes. Hence judicial legitimisation comes at a cost if it limits opportunities and stifles flexibility in policy choices and implementation.

Yet centralised policy-making in the UK has been diagnosed with its own legitimacy deficits. The New Labour government, which came to power in the UK in 1997, attempted to rebuild trust in the capabilities of central government by developing strategies to 'modernise government' (HM Government, 1999). One of the recommendations of the 1999 White Paper 'Modernising Government' was for central government to draw more explicitly on scientific evidence and seek expert advice, in addition to being more 'outward looking' and better 'networked' within government (HM Government, 1999). While this agenda initially sprung from the progressive agenda of the 'Third Way', the demand on government and other public policy actors to demonstrate that policy decisions were supported by relevant scientific research has continued to provide a powerful narrative and strategy for legitimation, which in public health, with its proximity to evidence-based medicine, is perhaps particularly pertinent. However, the reliance on evidence has proven to be risky when the evidence base on the potential harms and benefits of policy options are still incomplete and emerging, as it is on e-cigarettes.

Regulating electronic cigarettes

E-cigarettes entered European markets in the mid-2000s and experienced a rapid increase in popularity. They had been on the radar of national regulators for some time before they came onto the agenda of the EU relatively late in the legislative process of developing the TPD. As the desire of the EU to adopt a comprehensive approach to e-cigarettes via the TPD emerged, the focus on

national governments became no less important for policy actors seeking to shape regulation given the crucial legislative role played by the Council of the European Union within the EU's Ordinary Legislative Procedure. Policy actors sought to influence positions of national governments – particularly those of politically powerful member-states such as the UK and Germany – in Council deliberations on the TPD. Consequently, the period between 2012 and 2016, when the TPD was finally transposed into national legislation, is a key timeframe for seeking to understand the ways in which policy actors sought to position themselves and influence, or legitimise, policy decisions on e-cigarettes in each country.

E-cigarettes sold within the European single market must either be licenced as medical devices or sold as tobacco products according to criteria set out within the TPD. In each case, a product approval is overseen in member-states by a designated 'competent authority'. In England, this is the Medicines and Healthcare Products Regulatory Agency (MHRA): an executive agency of the Department of Health. In Germany, the Federal Ministry of Food and Agriculture oversees the implementation of the TPD, while the Federal Institute for Drugs and Medical Devices (BfArM) is responsible for pharmaceutical licensing. The route to market chosen for a given product affects various aspects of the devices, most notably the concentration of nicotine solutions they use and the ways in which they can be marketed and advertised. Devices sold as tobacco products can contain liquids with a maximum concentration of 20 mg/ml of nicotine and a maximum cartridge volume of 2 ml (ASH, 2016). Liquids with nicotine concentrations above this threshold require a licence as a pharmaceutical; and their containers qualify as medical devices. Only products licenced as pharmaceutical /medical device can make claims about their health effects in marketing materials. The TPD also contains a number of requirements for the packaging and warning labels on liquids and devices are covered by regulations relating to cross border advertising and marketing of tobacco products related to the functioning of the single market.

[Table 1 about here]

National governments remain responsible for other areas of e-cigarette policy without cross border effects including minimum purchase ages for e-cigarettes and rules relating to their use in public places. Both England and Germany passed legislation to ban the sale of e-cigarettes to those under 18 years of age, bringing their conditions of sale into line with tobacco products. Both governments also decided against extending clean air legislation to include e-cigarettes, although private owners of premises (e.g. public houses, bars and restaurants) and other public and private bodies (such as train operating companies) have taken unilateral action to ban the use of e-cigarettes on their premises.

[Table 2 about here]

Yet despite the substantial communalities in the policy decisions taken, both countries differed substantially in the degree of controversy that e-cigarettes policy attracted. In England, the topic has proven to be highly controversial, dividing the public health and tobacco control communities. This was even more astonishing as these groups had previously collaborated successfully and over a long period to achieve increasingly stringent tobacco control policies including a smoking ban in public places (Arnott et al., 2007). Yet in the case of e-cigarettes this collaboration fractured. On one side of the argument, public health advocates highlighted the potential health risks from e-cigarette consumption and the danger of e-cigarettes undoing previous tobacco control efforts (principally by renormalizing smoking, undermining clean air legislation and circumventing current restrictions on advertising and branding). Proponents also worried about the tobacco industry strategically using e-cigarettes to re-claim the market for cigarettes and to re-establish their diminished influence in the policy making process (José, 2015; McKee et al., 2014; Watson and Forshaw, 2015). In their view, it was obvious that the ultimate aim for the tobacco industry was to maintain smoking rates through the recruitment of new smokers (the so-called ‘gateway hypothesis’) and deterring current smokers from quitting (McKee, 2013).

In contrast, proponents of a harm reduction approach argued that e-cigarettes might provide an alternative to smoking for those addicted to nicotine without exposing them to many of the health risks associated with burning tobacco. For them, e-cigarettes potentially provided an approach to reducing harm to smokers and hence a solution to a public health problem that would potentially be more cost effective than publicly funded cessation programmes (Brown 2015; Gostin, 2015; McNeill et al., 2014; O’Connor and Fenton, 2015).

In Germany, in contrast, the harm reduction argument was largely absent in public discourse. E-cigarette regulation is strongly opposed by vaping activists as articulated in various internet fora and the *Verband des e-Zigarettenhandels* (VdeH), the trade association of e-cigarette producers and sellers, lobbies for regulatory restraint. However, in wider public discourse the argument for promoting e-cigarettes was much less visible and was made less forcefully by proponents.

Methods

This paper aims to explain the difference in the degree of policy controversy in England and Germany. It uses semi-structured interviews with key policy actors in the UK and Germany engaged with the issue of e-cigarette regulation. Data collected from interviews were supplemented by

information gained from policy documents, court decisions, and media articles from a range of outlets including the BBC, The Telegraph and The Guardian (for England) and Spiegel online, Der Spiegel, Die Zeit, die Welt, Tageszeitung (for Germany).

Interviewees were identified through a review of relevant policy documents and publications on the issue and through attendance at e-cigarette conferences and events. In total, 16 interviews were carried out - nine in the UK and seven in Germany. Interviews were conducted in person or over the phone and lasted around an hour in length each. Most interviews were conducted jointly by the authors in the native language of respondents; a small number of interviews were conducted by the first author only.

All interviews were transcribed and analysed in the original language. Quotes from the German interviews presented here were translated by the authors. Respondents were offered anonymity and confidentiality for their responses given the highly politicised nature of the policy debates. As such quotes are only attributed in ways which protect respondents from identification, referring only to the country and the sector in which they work or the type of organisation they represent where this is relevant to the status of the information they supply and its evaluation by the reader. Quotes given are designed as illustrative examples of the points made with indications given of how widely shared the viewpoints were amongst respondents.

The analysis of the transcripts of the UK interviews were led by BH and of interviews in Germany by SE. Themes were generated iteratively through document analysis, engagement with relevant literatures and the analysis of the interviews. The authors liaised on the identification of codes and the coding process throughout the analysis phase. SE led the comparative analysis and wrote the first draft of the paper which was then edited, revised and refined by BH. Authors discussed themes and the emerging comparative framework throughout the analysis and writing process.

Existing tobacco control policies and their effects on markets and consumption

The first set of factors relates to the differences in existing tobacco control policies and their effects on the tobacco and e-cigarette markets that informed the scale, and intensity, of the debate surrounding the regulation of e-cigarettes in both countries, with e-cigarettes being a substantially more controversial in England than in Germany. This analysis identified four interrelated themes that may explain the difference in in the perceived relevance of e-cigarettes as a concern for public health: (1) the differences in existing tobacco control legislation (and thus the ability to sell and

market conventional cigarettes) that provides the backdrop for the regulation of e-cigarettes; (2) the prevalence of e-cigarette consumption and the growth of the market for e-cigarette; (3) the involvement of 'big tobacco' firms in this market; and (4) the propensity of the public health community to advocate for, and scrutinise, public health policy decisions, and to involve themselves in public debate.

(1) While both countries have put in place increasingly stringent tobacco control measures over time, England has implemented more comprehensive tobacco control legislation than Germany and, as a result, smoking prevalence has fallen more rapidly. England has implemented a comprehensive set of tobacco control measures including legislation to prohibit smoking in public places, bans on advertising and promotion of cigarettes, and stringent rules on packaging and labelling. Germany has made significant steps to discourage smoking in recent years, yet these efforts less comprehensive and regionally fragmented (e.g. bans on smoking in bars and restaurants fall under the remit of the 16 *Länder*). Germany is now the only country in the EU that still allows billboard advertising of cigarettes and only recently introduced images as warning labels on cigarette packages. As a result, the smoking rate in the UK has now fallen to under 20 percent of people aged 15 years and over, while in Germany, smoking rates among adults are still at almost 28 percent (WHO 2016). It follows that smokers in Germany experience less pressure to quit smoking or to switch to alternative sources of nicotine than in the UK. It also seems plausible that the tobacco industry has less clear incentives in Germany than in other markets to enter the e-cigarette market as this would risk undercutting its current, and still highly successful, business model.

(2) Current numbers of e-cigarette users rely on estimates, but data from a 2016 survey in Germany suggests that less than one percent of people over the age of 16 years were using e-cigarettes at the time (DKFZ, 2016). In England, it is estimated that over 6 percent of adults used e-cigarettes, with numbers having risen rapidly from 700,000 in 2012 to 2.8 million in 2016 (ASH 2016). This led to a sense of urgency in tackling e-cigarette regulation in the face of their rapidly increasing popularity (as reflected in newspaper articles, e.g. The Guardian (2014) and The Telegraph (2015). In Germany, regulatory authorities became aware of e-cigarettes early in the mid-2000s, but user numbers have remained relatively low and interviewees (a state policy-maker and a researcher) were divided in their judgement as to whether e-cigarettes were a noticeable presence and a reason for concern.

"I only noticed this [people using e-cigarettes] in the beginning as a little hype, somewhere in my personal environment, but since then the topic has completely disappeared. I do not see them at all. And we have not been asked to address any legal concerns yet either." (GE 15)

“Yes, a few years ago I did not see much of them in the streets and this was more something ... well, a procedure that we heard about from the US or from reports, but this has changed. If you now walk through the city, there are more people who use e-cigarettes, at bus stops for example. So this is what I have noticed in the streets.” (GE 19)

(3) Concerns in England were also triggered by the fact that large tobacco companies had begun to invest heavily in the e-cigarette market (McKee, 2012; Gornall, 2015). In Germany, in contrast, e-cigarettes were still seen as niche products, as most products on sale were imports from China in addition to a few products manufactured by a number of small home-grown companies (e.g. Red Kiwi).

“E-cigarette have essentially been marketed for four years now by individual tobacco firms, they are promoted not yet by large but by small [firms]. To put it simply, they are not produced by large companies but by small niche producers, almost always in China, and are sold here on the grey market.” (GE 16)

The absence of big tobacco firms cannot be taken as a certainty, as the market for e-cigarettes in Germany is highly opaque (e.g. the ownership of brands is often not visible; the trade organisation for e-cigarette producers and sellers does not publish a list of its members). If the celebratory tone of recent press releases of the association of e-cigarette producers and sellers in Germany is any indication, the market is growing rapidly (VDEH, 2016). However, interviewees were not aware of any presence of the tobacco industry in the market. For some, this resonated with previous experience of tobacco companies having substantial influence on policy-making in Germany, which they used to stymie attempts of more stringent tobacco control:

“I think, in Germany, there are rarely concerns that the industry could have too much influence, I say this very clearly. I think politics (i.e. politicians) simply does not care. [The perception is that] They [i.e. the firms] should be economically successful, they should make money, they should bring in plenty of tobacco taxes, although we know that this is not really that much given that we would also reduce the [burden of] disease. And everything else is not of interest to them [...]. There is no concern that the industry could be too influential.” (GE 19)

In England, in contrast, engagement with the tobacco industry has been anathema for policy-makers for more than a decade and the risk of large tobacco companies gaining influence over the e-cigarette market has been an expressed concern among a number of public health researchers and advocates (Gornall, 2015). In relation to e-cigarettes, proximity to the tobacco industry has become a major bone of contention within the public health community (e.g. Lancet, 2015; Glantz, 2015).

(4) England has a sizeable, confident, and historically well-grounded public health community that has made tobacco control one of its cornerstones and key achievements. This community works across disciplinary and professional boundaries and includes academic researchers, advocacy organisations, charitable and governmental research funders, as well as the medical community.

These actors had successfully cooperated in the past to build the evidence base in support of stringent tobacco control (Arnott, 2007). By comparison, the relevant public health community in Germany is fragmented and small, both by academic standards and in relation to Germany's population size. It is often said that in Germany public health was discredited through its association with the ideology of *Rassenhygiene* under the Third Reich. Although the argument is likely to be overstretched to explain the lack of presence in public health debate, the reputational damage has persistent, and in the seventy years since, 'Public Health Germany', as one interviewee noted, has not been able to overcome the fragmentation of its efforts. This is notable in relation to tobacco control, with the German Centre for Cancer Research (DKFZ), a Collaborating Centre of WHO, taking a prominent, and largely singular, role in conducting research on the risks and prevalence of smoking, the influence and tactics of the tobacco industry, and the effects of tobacco control interventions. The DKFZ is now an established and influential policy actor that is well networked with both the media and policy-makers in government. Yet it is perceived, including by actors within the organisation itself, as a lone voice, dominating a highly fragmented public health community that does not have the critical mass, cohesion, or funding that would compare well with public health advocacy in England.

„We find it difficult to deal with public health in Germany because of our history, so the Third Reich, and its perversion of the idea of public health. It is surely so that public health has gradually become more important again in Germany and research has certainly contributed to this, but it is still a very slow process.“ (GE 19)

As a result, there was only one (dominant) policy actor in Germany and this actor advocated stringent regulation of e-cigarettes, while in England there were a number of competing voices within the public health sector, representing a range of perspective on the potential risks and benefits of e-cigarettes.

Institutional contexts and pathways

The second set of factors concerns differences relating to the process of making e-cigarettes regulation and the policy actors involved in this process and debates, suggesting institutional differences in policy-making and differences in policy styles between the two countries.

In Germany, federal regulatory authorities became aware of e-cigarettes from the mid-2000s. In 2008, the Federal Institute for Risk Assessment (BfR) published an assessment report on e-cigarettes, taking a cautionary approach and warning consumers about their potential but yet unclear health risks. Other federal agencies such as the Federal Institute for Drugs and Medical Devices (BfArM) and

the Federal Office of Consumer Protection and Food Safety (BVL) followed suit, issuing statements on the regulatory options for e-cigarettes. Yet at this stage it was not clear how e-cigarettes could be regulated (e.g. as a pharmaceutical, tobacco product or consumer product) and by which part of the administration this should be developed. BVL declared that e-cigarettes could not be considered a tobacco product while the BfArM came to the conclusion that e-cigarettes could be regulated as pharmaceuticals because of their pharmacological effects (BfArM, 2013).

Concerns about e-cigarettes were also shared by the *Länder*, some of whom requested clarification from federal authorities about how to deal with e-cigarettes. In December 2011, the health minister of North Rhine Westphalia (NRW), Barbara Steffens, warned that e-cigarettes were associated with unclear health risks and that selling e-cigarettes was illegal (MGEPA, 2011). E-cigarette sales were only permitted if they had received a pharmaceutical licence. Yet this position became untenable when a producer and a vendor took the NRW minister to court and the court (specialised on administrative law) ruled that e-cigarettes could not be classified as pharmaceuticals. More specifically, the court judged that “there is no scientific evidence that [e-cigarettes] are effective in treating nicotine addiction”, hence did not qualify as a pharmaceutical (Administrative Court, Cologne, 7 K 3169/11). The court also ruled that e-cigarettes could not be considered tobacco products, which meant that existing regulation on cigarettes did not apply to them either. By rejecting these classifications, the court (and the state level court that confirmed the decision) reduced the options for public authorities to regulate e-cigarettes as it was not possible to apply an existing body of law to the new product. It became apparent that e-cigarettes required a new legislative initiative, yet this stalled at national level when it became clear the e-cigarettes would be part of the emerging EU directive.

In England, the Medical and Healthcare Products Regulatory Agency (MHRA) emerged as the main authority seeking to assume responsibility for regulating e-cigarettes. The agency initially declared its intention to regulate e-cigarettes as pharmaceuticals, but from 2013, Public Health England (PHE), a newly created executive agency, was mandated with gathering the evidence on e-cigarettes as a priority issue. Subsequently, PHE commissioned a series of reports on the topic in 2014 and 2015, aimed at bring together the existing evidence on e-cigarettes (McNeill et al., 2015, Britton and Bogdanovica, 2014, Bauld et al., 2014). One report, published in August 2015, claimed that e-cigarettes were ‘95% safer’ than conventional cigarettes (McNeill et al., 2015). These assertions led to a major controversy between PHE and researchers who advocated a harm reduction approach to regulation and public health researchers who questioned the validity of the evidence in support of the claim.

This specific controversy did not take place in the German research community. While a few interviewees supported the position that e-cigarettes could potentially reduce the health risk of smokers if they were to switch to e-cigarettes, this position was not widely held and not promoted by a federal or state government actor. Representatives of government administrations or agencies advocated a cautionary approach, while pointing out the remaining unknowns relating to the effects of e-cigarettes use as a quitting aid.

“Then there was the health research or public health oriented debate on e-cigarettes. Is this a healthy product compared to smoking? It surely is healthier. But we did not want to step into this trap and say that e-cigarettes are harmless. Therefore, we do not advise to smoke [sic] e-cigarettes. If a smoker of many years thinks he can use e-cigarettes as an alternative, then he can do so. But he will not get the approval of health policy makers, especially not for children and young people. And therefore we are very careful, especially because of the unknown ingredients of e-cigarettes.” (GE 16).

In line with their different administrative traditions, England and Germany also applied different approaches to transposing the TPD into national legislation. In England, this was done by executive order only, issued by the Department of Health on behalf of the Government. In Germany, the transposition required new primary legislation, passed by parliament. The Federal Ministry of Food and Agriculture, responsible for the implementation of the TPD, developed a draft bill (*Referentenentwurf*) in June 2015 that was consequently discussed and amended by several federal ministries involved (e.g. Ministries of Health and Finance), the governing political parties, the Cabinet, and the Chancellery. The most obvious change made in the final version of the Act on Tobacco Products (*Tabakerzeugnisgesetz*) was the deletion of the ban on billboard and cinema advertising for both conventional and electronic cigarettes, which had been proposed in the draft bill by the Federal Ministry of Health; the relevant paragraph disappeared in the final version of the law. As a result, Germany continues to be in breach of the Framework Convention on Tobacco Control despite being one of its signatories.

Governments in both countries, however, used the opportunity of the TPD to tighten the minimum purchase ages for e-cigarettes. As a result, both countries developed the same measures in place to regulate e-cigarettes, although the processes leading to these decisions, the policy actors involved and the intensity of controversy surrounding e-cigarettes were substantially different.

Routes to legitimising policy positions

Finally, the debate surrounding e-cigarette policy also highlights different strategies of legitimising policy positions, which are analysed here as a third set of factors. For the purpose of this analysis,

such positions are presented either as contributions to debate by advocates/critics or as policy decisions made by governments/parliaments.

In Germany, prior to the TPD, the search for approaches to legitimating e-cigarette regulation resulted in a period of uncertainty about which public authority was responsible for the new technology. While e-cigarettes came onto the radar of a number of government agencies early in the 2000s, it was not clear who would be responsible and which body of law would relate to e-cigarettes. BfArM and state health ministries tried to step up to the challenge but the position was challenged successfully in court.

Indeed, conflict resolution between these different positions was sought through court cases, in which courts rejected several options of classifying e-cigarettes, yet without giving guidance on how e-cigarettes should be regulated if existing law did not apply. While this practice is reflective of the 'legalistic' political culture in Germany, it is also problematic as the approach closed options that had previously been seen as a desirable viable position, especially by tobacco control advocates such as the DKFZ. Courts made reference to scientific evidence on e-cigarettes, noting the absence of proof of a curative benefit, yet the legitimacy of the decision arose from the status of courts within the state rather than their particular way of reasoning.

In England, in contrast, the entire debate about regulating e-cigarettes revolved around the interpretation of evidence. Most obviously evidence emerged as a source of legitimacy for the policy positions adopted on the issue. All respondents, regardless of the types of organisation they represented or the position they adopted on the issue at hand, adhered to the principle of evidence based policy making and claimed to be led by the evidence in developing their positions on the issue. For example, a representative of a health NGO was asked how their organisation developed its position on e-cigarettes:

"So, for me, I think following the evidence and trying to be fleet of foot enough to move as the evidence changes or becomes clearer is important. So, from our perspective, I suppose, [name of organisation] hasn't taken a strong position for or against e-cigarettes, but we have said that we see potential opportunities in people using them in the way that they use nicotine replacement therapy to cut down and quit from lit smoke tobacco, or people who are not willing or able to quit tobacco switching onto them entirely, and then it's harm reduction, because they're never going to be as harmful as tobacco." (EN 1).

At the same time, many respondents criticised other policy actors for failing to follow the evidence base. As one researcher in the field commented:

"So, when we have public health scientists who are supposed to be trusted individuals, or public health bodies that are, for whatever reason, you know, and I completely understand the motives, but are not interpreting the science correctly, and are using double standards... you know, if we take, for example, the discussion over plain packaging,

which I fully support, or the evidence relating to e-cigarettes or the evidence relating to a drug like Varenicline, [...], you know, it's very interesting seeing people applying really different standards of evidence for what they are willing to believe.”(EN 6).

PHE in particular put itself in the firing line when publishing several reports that summarised the evidence on the risks and benefits of e-cigarettes. Its conclusion, based on these reviews, that e-cigarettes should not be regulated too strictly in order not to discourage heavy smokers to use e-cigarettes instead of tobacco was fiercely contested by public health researchers who felt that significant parts of the evidence relevant to decisions on e-cigarettes had purposefully been cast aside, especially with regard to the role of tobacco companies in creating a new market for themselves.

Another strategy of PHE to legitimate its position and influence the discourse that increasingly had spiralled out of control was to build a consensus among researchers, advocates and policy-makers. This strategy had worked well in the past and was seen as one of the key factors of previous successes in tobacco control (Arnott et al., 2007). As one official explained:

“That's why we were in a position in October when all the key organisations were able to come together and say actually we think PHE are right, because we'd been talking for years. And yes, there were other people who weren't involved in that discussion for years, who had either not been invited or just weren't interested or had chosen not to be part of it, they were outside that consensus and they made a lot of noise at the consensus. But it didn't really influence the consensus. So yes, the evidence based consensus building project, back on harm reduction, yes, it's all done in PHE but it is the way PHE works.” (EN 5).

However, the difficulty was that not everyone agreed, therefore the 'consensus' became an agreement among some rather than a position shared by all relevant policy actors.

Efforts at building consensus were also made in Germany, yet this was undertaken by advocates rather than government organisations. This approach resulted in the publication of a 'Memorandum' that reiterated the demand for a precautionary approach stating that e-cigarettes posed significant risks to public health and were not proven to be effective as a quitting aid (DKFZ, 2015). This document was developed by two tobacco control advocates, the DKFZ and the *Aktionsbündnis Nichtraucher*, and signed by 48 medical societies, charities and tobacco control advocacy organisations. The key purpose of this consensus was to demonstrate to the German government that all relevant actors in the medical community were in support of comprehensive regulation.

In England, the attempt to create a consensus based on evidence resulted in the publication of a report that contained the widely publicised claim that e-cigarettes were '95% safer' than conventional cigarettes (McNeill and Hayek 2015). The vehement criticism of the report, and the 95

figure in particular, by researchers and other actors in the field, appeared to undermine any claims to there being an emerging consensus on the identification and interpretation of existing evidence on e-cigarettes or the appropriate policy responses to them (Lancet 2015; Capewell and McKee 2015). The idea of an emerging consensus is closely allied to the identification of a core group of scholars considered to be experts on the issue, whilst the credentials of those outside of this is called into question. As one researcher commented:

“You know... people who actually work in the field primarily are of one view. And then where the controversy is, is by and large, very high profile public health people who don't actually work in the field. [...] And it's actually a relatively small number of people here who are not really tobacco experts. [One colleague] is someone who is in the field and who takes a similar view but [...] we're good friends and we don't really have a disagreement because [they say], I hear what you're saying around the evidence, I've got no problem with that. However, these are my worries. Absolutely fine. And so we can have a friendly, you know, discussion about it. [...] But I think that my hypothesis is that there is a lot of tobacco control experts in this country. And they are almost all of pretty much the same view.” (EN 6)

The difficulty, and ultimately failure, of creating agreement around 'the evidence' highlights a particular understanding of the role and purpose of scientific research in relation to policy-making, with some protagonists arguably holding naive rationalist view of a linear relationship between research and policy. This interpretation of events, however, misunderstands the dispute as a disagreement about scientific facts while it is more likely to be a disagreement on policy objectives, propelled by a deep mistrust of tobacco companies and a fear of undoing the hard-won achievements of previous tobacco control effects.

This controversy between tobacco control and harm reduction advocates within the public health community, and its recourse to evidence claims, was much more limited in Germany. This is perhaps unsurprising given fragmentation of the public health community, with the DKFZ being the only, and by now dominant, advocate in the field that has put forward any arguments relating to the potential harms of e-cigarettes. These claims have drawn heavily on evidence, such studies on the toxicity of liquids, the effects of dual usage and e-cigarette usage (DKFZ, 2014; DKFZ, 2014; DKFZ, 2016), and have found a substantial media and policy audience, while other, contrasting positions, although mentioned in private in interviews, have had little resonance with the media and government.

Discussion and conclusion

This paper compared the factors that explain why e-cigarettes regulation has become much more controversial in England than in Germany. More specifically, the paper has identified differences in existing tobacco control and market develop that shape the prominence the issue, institutional

context and pathways of decision-making, and in forms of legitimating policy positions as contributing to e-cigarette regulation becoming strongly contested in England, especially within the public health community, while attracting only limited controversy in Germany.

Explaining the presence or absence of debate on specific policy issues in different national contexts is a difficult undertaking, given the complex array of factors influencing policy debates. In the case of e-cigarettes, it is plausible that differences in previous efforts to control tobacco consumption have had an effect on the motivation of tobacco firms to enter the market for e-cigarettes and that such market activity provokes suspicion from public health advocates. It is also likely that public health advocates have learned lessons from previous encounters with the tobacco industry that inform these concerns (José, 2015; McKee et al., 2014; Watson and Forshaw, 2015). From a comparative perspective, it is then possible to argue that e-cigarettes regulation has been of a stronger concern to the public health community in England than in Germany, where the public health community is less influential, and perhaps less interested, in stimulating public debate. However, it is impossible to test this chain of reasoning and so it remains only a working hypothesis. The absence of controversy is more difficult to explain than its presence.

The analysis of institutional pathways, in contrast, clearly resonates with the existing literature on national differences between policy actors, processes and policy styles. Establishing who is responsible for regulating a novel technology is more complex in Germany given the larger number of potential regulators and the reliance on law and courts is more prominent than in England where policy development, including the transposition of EU law, is a matter of governmental decision-making only. This leaves England with more flexibility in devising policy options (with the exception of those already dealt with at EU level) than Germany where court rulings closed down several regulatory options prior to the TPD (Landfried, 1992). The question is, however, whether this openness to generate options in the absence of opposition from veto players also leaves more space for controversy, which may depend on whether a policy solution proposed by the executive (here PHE) is seen as legitimate. Again there are limits as to whether this can be established through this analysis, as other causes may be possible, for example, court rulings that have stimulated rather than ended debate (e.g. in relation to the recent revision of inheritance law in Germany; FAZ, 2016).

In both countries, efforts were made by some policy actors to engineer a consensus in support of a preferred policy option with reference to scientific evidence: in England, this was a strategy employed by PHE in support of the harm reduction approach, in Germany the DKFZ brought together 50 medical societies and tobacco control organisations to demand more stringent tobacco control and e-cigarette regulation. However, the contestation of the evidence in support of policy

options undermined the consensus in England by bringing to the fore uncertainties about the risks and benefits potentially associated with e-cigarettes in the absence of conclusive evidence. While both sides of the argument used evidentiary claims to support their positions, diverging views on policy objectives, and values and beliefs underpinning these objectives, while couched in terms of evidence, were at the core of the disagreement (e.g. views on the potential risks and benefits of regulation; attitudes towards the tobacco industry). In Germany, disagreements about values were also articulated in court cases, yet the harm reduction argument held little currency both with courts and with policy-makers in government or parliament. While courts rejected regulatory options, noting the absence of supporting evidence, they did not provide a solution to the regulatory problem. Referring to existing law proved insufficient to resolve a conflict over the regulation of a novel technology. Hence there is a parallel between the shortcomings of legitimising decisions through scientific evidence and through recourse to the law as both are retrospective in orientation and ill-equipped to deal with new challenges, emerging risk and uncertainty, which may require a more flexible, adaptive approach to governance (Renn and Klinke, 2013).

In comparing the presence and absence of debate about e-cigarette regulation in England and Germany, this paper underlines the importance of considering the complex interplay of factors as diverse as recent developments in regulation and markets, historical trajectories of academic and advocacy communities, institutional context that shape decision-making pathways, and established routes for legitimisation. The paper therefore highlights the complex interplay of political, institutional and cultural factors in explaining differences in regulatory decision-making.

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Table 1**Regulation included in the Tobacco Products Directive relating to e-cigarettes**

Notification of 'competent authorities' 6 months before launch of new product
Nicotine content no higher than 20mg per ml
Health warnings and consumer information
Ban on cross-border advertising
Manufacturing and product standards, e.g. product safety, ingredients, packaging
Monitoring of compliance

Table 2**Regulation not included in the Tobacco Products Directive**

England	Germany
No ban on flavours	No ban on flavours
Ban on sales to minors	Ban on sales to minors
No ban on non-cross border advertising	No ban on non-cross border advertising
Regulation under medicinal licence for liquids containing nicotine higher than 20mg/ml	Regulation under medicinal licence for liquids containing nicotine higher than 20mg/ml
No restriction on smoking in public places	No restriction on smoking in public places