Political Perspectives 2012, volume 6 (1), 86-104

Europeanisation through soft law:

the future of EU health policy?

Eleanor Brooks

Lancaster University

E.brooks@lancaster.ac.uk

Abstract

The last two decades have seen the emergence of what is widely labelled a 'European' health policy sphere. The expansion of this traditionally national field of governance has been supported by a comparatively weak legal framework, which grants the European Union (EU) very little in the way of formal competence, instead reserving the majority of power for member states. Given the resistance of national governments to the involvement of Community institutions in this politically and culturally sensitive area, how then has such a mandate expansion occurred? The answer, at least in part, lies in the proliferating use of soft law. Employing a combination of non-binding guidelines, mutual learning and peer review, soft mechanisms circumvent almost all of the traditional impediments to 'harder' progress, such as Community legislation or treaty revision, and enables the incremental 'Europeanisation' of sensitive policy areas. This article will assert that a European health field has emerged as a result of gradual but persistent Europeanisation through soft law. It will present an analysis of the use of soft law in European health policy through a Europeanisation framework and examine how the integration, governance and construction of EU health policy is affected by soft law instruments. Finally, it will ask what this implies for the future of this fledgling policy area and suggest that it is soft law, rather than treaty reform or EU legislation, which will play the leading role in the continued development of a European health policy.

Key Words: soft law, health policy, Europeanisation, EU Health Strategy, public health, health governance, democratic deficit

Introduction

Social, and in particular health, policy in the European Union (EU) has reached a crucial point in its development. Writing in 2010, Leibfried (2010: 264) stated that 'EU legislative activity is now at least as extensive as federal social policy activity was on the eve of the US New Deal in the 1930s'. In health policy specifically, Greer (2008: 219) describes the EU's position as a 'critical juncture', where seemingly minor policies made in the current climate

will come to define and delimit the future Europeanisation of this underdeveloped policy sphere. Though these characterisations suggest an optimistic outlook for the progression of health policy in general, this opportunity has remained unmatched by legal competence. Yet despite restricted formal EU competence, health policy has proven remarkably susceptible to the dynamics of integration (Steffen *et al.*, 2005: 3). Given the absence of legal competence at the European level, how then is such Europeanisation occurring?

There are two primary answers to the above question. Firstly, there are a number of ancillary policies which impinge upon member states' sovereignty in administering national health systems, not least of all those concerned with the Single Market. Some of these policies have been exploited by the Commission in order to extend its mandate indirectly; others have been created in response to rulings by the Court of Justice of the EU, referred to as the Court of Justice (CoJ). Cumulatively, a process of 'competence creep' has allowed the Commission, with support from the Court, to manipulate its existing mandate and generate a new set of *de facto* health competencies (Cram, 1997: 46). Moving away from direct legal provisions, however, the institutions have forged a second path in the Europeanisation of national health systems. The use of soft law instruments in policy-making has proliferated in recent years; writing in the mid-1990s, Flynn (cited in Cini, 2001: 193) declared the EU to be entering an 'era of soft law'. Using a combination of non-binding guidelines, mutual learning and peer review, soft law circumvents almost all of the traditional, political impediments that hinder 'harder' progress in the health field and in integration more generally. It is this second process on which this study will focus.

Attempts to define soft law have revealed a number of different interpretations, each trying to untangle the central contradiction of the concept – 'soft law without legal effects is not law and soft law with legal effects is hard law' (Senden, 2004: 109). The dominant definition, cited in most academic works on the subject, is given by Snyder (1993: 32), who asserts that soft laws are '...rules of conduct which, in principle, have no legally binding force but which nevertheless may have practical effects'. Turning to the treaty definitions, Article 288 TFEU (previously Article 249 TEC) declares regulations, directives and decisions to be binding legal acts, but when listing non-binding instruments, refers only to recommendations and opinions. Other non-binding measures, such as conclusions and declarations, do not appear in the treaty texts, but the EU draws on several voluntary tools, including: Council declarations; peer review, monitoring and evaluation mechanisms; and Green and White Papers (Faulkner *et al.*, 2005: 52). The Court has also identified a number of sources, including but not limited to communications, resolutions, codes of conduct, frameworks, Commission guidelines, and documents of social, private, and academic actors (Di Robilant, 2006: 500; Cini, 2001: 195).

Throughout the article, a distinction is made between *public health* policy, on which the article will focus, and areas of *healthcare* and *health services* policy. The latter fields, which deal with treatment of individuals as opposed to the management of collective health, are more commonly subject to the first path of Europeanisation outlined above, exhibiting integration through case law and exposure to internal market principles, whereas public health is increasingly governed by soft law (Steffen *et al.*, 2005: 5; Greer, 2008: 219). Steffen *et al.* (*ibid.*) note that these two fields intertwine at the national level but are made distinct at

the European level by the division of competencies in the treaties. Therefore, this article will concentrate primarily on institutional dynamics – the treaty provisions and institutional structures that enforce this division and provide a role for soft law as an institutional process.

Europeanisation is conceived as a process of construction, diffusion and institutionalisation of both direct and soft mechanisms, which can occur through top-down, bottom-up, and horizontal dynamics. This article will argue that as the Europeanisation of health policy shifts from being a vertical (top-down and bottom-up), institution-building process to encompass horizontal mechanisms, the balance between the use of hard and soft law is shifting in favour of the latter. In this way, it brings together the literature on the role of soft law in EU policy-making with that on Europeanisation.

Part one will give a brief overview of European health policy and the mechanisms, both hard and soft, currently used in this field. Part two will review the theoretical perspective of Europeanisation, before part three presents a case study of the EU Health Strategy and the role of soft law therein. Finally, an analysis of the theoretical and practical implications of soft law will be followed by a brief conclusion, suggesting that soft mechanisms will play a leading role in the future development of European health policy.

Europeanisation through soft law

Since the early 2000s, research on Europeanisation has breathed new life into the older debates and is now used as an umbrella theory for understanding integration, policy-making and EU governance. Important caveats here are made by Olsen (2002: 921 *et seq*), who views Europeanisation as an 'attention-directing device' but not an explanatory theory in itself, and Bulmer (2007: 46 *et seq*), who emphasises the need to embed concepts of Europeanisation into the wider theoretical context of integration. Moving past the traditional divisions between integration theory, governance analysis and critical perspectives on the EU, Europeanisation provides an illustrative framework through which to evaluate the role of soft law. As a relatively young concept, however, its meaning is far from solidified. Most literature on the subject opens with a discussion of its definition, stating the importance of conceptual analysis (citing Satori, 1970) and highlighting the risk of conceptual stretching. Early contributions focused on downward pressure from the EU (see Ladrech, 1994 and Bulmer and Burch, 1998), but later works increasingly highlighted the two-way relationship between member states and the EU, characterised as circular, as opposed to top-down or bottom-up, Europeanisation (see Börzel, 2001 and Bulmer and Burch, 2001). More recently, Europeanisation is increasingly being used to study enlargement, allowing for an examination of adaption '…as a condition for rather than a consequence of membership' (Börzel and Risse, 2012: 192). Works in the early 2000s by Olsen (2002), as well as Buller and Gamble (2002),

sought to capture the field and both identified five similar uses and definitions of Europeanisation among the literature. These generally refer to: the development of institutions and governance at the EU level; the export of European forms of governance and political organisation; the penetration of domestic politics by EU policy-making; the achievement of the political unification of Europe; and a smokescreen for domestic political manoeuvres. Some specific explanations and variations of these definitions are examined below, along with their implications for the use of soft law mechanisms in the Europeanisation of health policy.

Börzel and Risse (2012: 195) divide the common usages outlined above into EU-specific and non-EU specific categories and integrate the latter with the literature on diffusion. In doing so, they identify direct and soft mechanisms of diffusion. The former are characterised as legal coercion and operate through the case law of the CoJ or through EU directives harmonising national legislations. However, since opportunities for exerting direct influence are decreasing, Börzel and Risse argue, the EU has become less of a promoter and more a model of institutional solutions. This softer mechanism of capacity-building and socialisation involves diffusion through emulation, avoiding active promotion of EU models but inducing domestic reform indirectly. Whilst Börzel and Risse are focusing on the export of European models outside of the member states, the role they envisage for soft law in this process is still of relevance to health policy. Mechanisms such as the Open Method of Coordination (OMC) operate as platforms for sharing of best practice and are designed to encourage emulation of successful public policy models, rather than promoting a single European model from above.

Focusing on one of the EU-specific definitions, namely that which refers to the domestic impacts of European-level institutions, Olsen (2002) considers the implications of soft law on patterns of national adaption. Whether EU institutions, identities and policies have impact and are complied with, he asserts, depends on many factors; among them, Olsen (2002: 933) highlights Jacobson's hypothesis that Europeanisation is more likely when they are based on hard law rather than soft law mechanisms (Jacobson, 2001: 20). Both authors acknowledge the need for empirical testing in this area, but recognise the potential impact of soft law in the Europeanisation process.

Examining the same 'domestic impacts' usage, Radaelli (2003b: 30) draws together similar definitions from the existing literature and argues that Europeanisation refers to:

'Processes of a) construction, b) diffusion, and c) institutionalisation of formal and informal rules, procedures, policy paradigms, styles, 'ways of doing things', and shared beliefs and norms which are first defined and consolidated in the making of EU public policy and politics and then incorporated in the logic of domestic discourse, identities, political structures, and public policies.'

In doing so, he differentiates Europeanisation from concepts of convergence, harmonisation, integration and policy formation. In the case of integration, in particular, Radaelli (2003b: 33) emphasises the distinction between these two, clearly linked, concepts. Integration theories, he asserts, are concerned with whether European integration strengthens or weakens the state,

or triggers multi-level dynamics. Europeanisation, on the other hand, takes a post-ontological focus and asks specific questions about processes and outcomes. Radaelli (2003a: 33 *et seq.*) also identifies vertical and horizontal mechanisms. The former are generally based on hard instruments, such as directives and decisions of the CoJ, whereas the latter are identified as 'soft framing mechanisms'. These do not create pressure in terms of adaption but they prepare the ground, change understandings and practice of governance and create the preconditions for the diffusion of shared ideas and policy paradigms. In particular, Radaelli highlights the importance of the OMC, which has been intrinsic to the development of European health policy in recent years, as an innovation in governance and soft law.

In the introduction to a comprehensive edited volume on the Europeanisation of health governance, Steffen *et al.* (2005: 5) identify five different perspectives of the concept. The first, which mirrors that identified by Olsen, and Buller and Gamble, refers to institution building at the European level – 'Health policy', Steffen *et al.* (*op. cit.*) note, 'seems to be concerned very little by this perspective, if at all, since member state governments still perceive it as a genuinely national policy field'. Having rejected one of the key definitions from the wider Europeanisation literature, they go on to identify four other conceptions, encompassing the dominant national adaption perspective, a circular and cyclical process of bottom-up and top-down dynamics, changes in domestic opportunity structures and soft processes of social learning and policy framing. Whilst concluding that '...the 'Europeanisation' of health policy is an ambivalent and extremely complex phenomenon operating on various levels, in different forms and with diverse effects', Steffen *et al.* (2005: 3) acknowledge a role for soft law in each of these perspectives.

Having walked through the emergence and evolution of the Europeanisation literature, its refinement within EU policy-making and, finally, its application in the specific field of health, the different conceptions can be brought together to reveal two common mechanisms. Firstly, using Steffen's description, the traditional conception and approach to Europeanisation in the health sphere has been one of national adaption and creation of EU-level institutions. Here hard law instruments are generally exercised through the top-down model, in which rules are made at the EU-level and national governments are required to implement legislation within the member states (Trubek and Trubek, 2005: 357; Versluis *et al.*, 2011: 61). This corresponds to Radaelli's distinction, which identifies vertical mechanisms as hard instruments, generating direct pressure for adaption. This first mechanism can be thought of as a combination of top-down and bottom-up processes, linked to Börzel and Risse's notion of institution-building. Secondly, however, the potential role of soft law in Europeanisation is increasingly acknowledged, particularly in circular and horizontal models (Lenschow, 2011: 58; Jacobsson, 2004: 89). This reflects Radaelli's description of horizontal mechanisms and the kind of indirect adaption pressures envisaged by Börzel and Risse. These soft instruments provide forums for the sharing and exchange of best practice, whilst peer review and shaming practices are used to encourage compliance in areas where agreement might not otherwise have been achieved. It is this second notion of Europeanisation which is gaining relevance in health policy, particularly with regards to soft law instruments.

Soft law in health policy

The '…robust public health mandate' provided for in Article 168 TFEU, '… is in sharp contrast with the restriction of Union competence in medical care and coverage', but in the sphere to which it applies it has been extensively utilised, with legislation currently in force in twenty-two individual areas of public health policy (Steffen et al, 2005: 11; European Commission Health Legislation). Of this legislation, however, only a fraction can be categorised as hard law, i.e. designated regulations, directives or decisions. The rest are soft instruments, lacking any legally binding force or enforcement mechanism.

Looking at the hard law provisions first, there are three main types. Firstly, the largest category is creational legislation, which sets up various agencies and provides a legal base for the Health Strategy and Health Programme initiatives. A second, smaller, group covers the EU's responses to new technologies and threats. These mainly concern electromagnetic fields and radioactive agents, as well as the prevention of BSE. Finally, it is the smallest category of hard law legislation which contains those instruments directly regulating health policy issues. These exist only in areas of cross-border healthcare, regulation of blood, tissue and organs, and tobacco advertising and manufacture. A search of the legislative archives indicates that the hard law in place here was all either preceded by or supplemented with soft measures, and constitutes only a small fraction of the EU activity in each particular policy sphere. In tobacco policy, for example, the directives in place regulate only matters connected to internal market law, such as advertising, manufacturing, sales and sponsorship; issues of treatment and prevention are left to softer methods, which are not always utilised by the member states (Toshkov, 2011: 7).

The majority of EU activity in the health field is therefore conducted through soft law mechanisms. Initiatives are in place in almost all the major sectors of public health policy, including: communicable diseases, particularly HIV/AIDS and pandemics; blood, tissue and organ regulation; tobacco; alcohol; nutrition and physical activity; and mental health. Measures are also in place to address some of the environmental determinants of health, such as socio-economic divisions, pollution-related disease and genetics and screening practices. On a wider, global scale, the EU works alongside international organisations and neighbourhood countries to improve global health and implement the many soft law instruments which exist at the international level, such as the WHO Framework Convention of Tobacco Control (WHO FCTC). One of the largest soft mechanisms at use in the health policy field is the Social Protection Committee (SPC), which acts as the health-variant of the OMC and was formed in 2006 to coordinate soft law approaches to pensions, social inclusion and health. As well as retaining the Nice 2000 objective of high quality, financially sustainable health systems with access for all, the SPC has three specific goals, namely social cohesion, equality and opportunity; effective interaction of the Lisbon objectives; and good governance. One particular area where the impact of the SPC can be clearly seen is in the development of EU cancer policy. The subject of the first ever EU Health Programme, cancer policy has grown to be one of the core issues in the EU's health policy portfolio (Trubek *et*

al., 2008: 814). Here, soft measures have routinely been used as leverage against 'difficult' member states and utilised in healthcare delivery by doctors across the Union (Hervey and Vanhercke, 2010: 88).

As discussed, soft law constitutes a large proportion of EU activity in the health policy field. The individual measures outlined above are, for the most part, brought together by the EU Health Strategy (the Strategy), an integrated framework of soft law instruments designed to promote European health. Itself a tool of soft governance, it identifies areas where action should be taken and ascertains whether such action is best taken at the national or the European level.

Case study: 'Fostering good health in an ageing Europe'

The White Paper outlining the EU Health Strategy was adopted by the Commission on 23 October 2007 (Commission, 2007e). Supported by the EU Health Programme, it provides a strategic and integrated framework for action at both the national and European levels, building upon existing objectives and guiding future policy principles. In itself it represents a huge step forward for European health policy; previous communications issued in 2000 and 2005 (Commission, 2005) lacked overall objectives and milestones, whereas the Strategy '...provides DG SANCO with a legal foundation and financial means for action' (EPHA, 19 October 2004).[1] As such, it '...can perhaps be said to mark the 'coming of age' of public health within the Commission' (Birt, 2008: 556).

Following a stakeholder consultation (Commission, 2006), an impact assessment (Commission, 2007d) and a review of European health policy (Commission, 2004), the Commission settled upon four principles and three objectives for the Strategy. These cover a broad spectrum of issues and policies and are supported by a vast number of soft governance mechanisms; this article will focus upon objective one, 'Fostering good health in an ageing Europe', which addresses actions concerning tobacco, nutrition, alcohol, mental health and other health determinants. The healthy ageing objective is by far the largest target of the Health Strategy, addressing the promotion of healthy lifestyles, the reduction of harmful behaviours and the prevention and treatment of specific illnesses (Commission, 2007e: 8). Of the principles and objectives listed in the Strategy, it can be considered to have the most direct impact upon the day-to-day health of EU citizens and to represent a more activist intervention than the other elements. For example, the promotion of health technologies or the protection from health threats are more abstract and collectively focused objectives, whereas fostering good health involves implementing a range of lifestyle changes for the individual. To promote healthy ageing and regulate the increase in national health expenditure, objective one sets out actions in four main categories of health determinant: cancer and rare diseases; organ donation and transplantation; older and younger persons' health; and tobacco, nutrition, alcohol, and mental health. Soft law has played a crucial but

[1] The total budget for the current Health Programme, which implements the Health Strategy, is €321,500,000.

different role in each of these areas and examining each in turn highlights the diverse outcomes that are produced by specific policy characteristics.

Cancer policy

The European Against Cancer (EAC) programme is the most widely recognised and longest running of the EU's special health programmes, pre-dating even the EU's treaty-based competence in public health (Randall, 2001: 97). As well the EAC programme, now in its fourth cycle, the EU has created a number of other soft mechanisms in this area, including the European Code Against Cancer, which outlines recommendations on how to take action to prevent the disease, the European Partnership for Action Against Cancer (EPAAC), which gathers stakeholders to identify and share information, a series of guidelines and a Council Recommendation (European Council, 2003) on cancer screening practices, and the European Cancer Health Indicator Project (EUROCHIP). Collectively, these instruments have become the model of soft governance in EU health policy, having supported a 9 per cent reduction in cancer incidence rates between 1987 and 2000 (Boyle *et al.*, 2003).

Organ donation and transplantation

The Health Strategy set targets regarding organ donation and transplantation which were both clear and well achieved. Building on the Commission Communication published in 2007 (Commission, 2007b), the Strategy called for a legal framework for safe and efficient practice, as well as an action plan (Commission, 2008a) for improving cooperation between member states. Proposals for both the hard and soft elements were brought forward in 2008 and a directive was adopted by the EU legislature in July 2010 (European Council, 2010). This case demonstrates the potential importance of soft law as an exploratory mechanism to frame an issue prior to the creation of hard legislation (López-Santana, 2006: 494).

Healthy ageing policy

The healthy ageing target is both vague and difficult to implement decisively. The Strategy aims to tackle health issues which affect the elder generation, as well funding initiatives concerning the health of children and young people. Accordingly, the Youth Health Initiative was launched in 2009 (see Health-EU Youth Health site), and several workshops on healthy ageing took place in 2010 (Commission, 2010a). These limited measures have provided little progress in comparison to that seen in areas such as cancer policy and most attention has in fact focused upon the statistical element of the objective – the Healthy Life Years indicator (see Healthy Life Indicators site). Taking into account not just life expectancy but the number of years lived in good health, this indicator provides a much more accurate and comprehensive tool for measurement and analysis, but represents the majority of progress made in this area.

Tobacco, alcohol, nutrition and mental health policy

This group of mechanisms is vast but a distinct contrast can be drawn between the success of the EU Platform for Action on Diet, Physical Activity and Health (Diet Platform of the EU) and the obstacles encountered by the Green Paper on smoke-free environments (SFEs) (Commission, 2007c) and the more general attempts to address the health threat posed by tobacco. The Diet Platform is held in similar regard to the EAC programme – bringing together stakeholders from the food industry, the health profession, advertising and media sectors and catering retailers, it has doubled in size since 2005 and had launched over 600 initiatives at local and regional levels by 2009 (European Commission, 2010b). Whilst decisions have not always worked in favour of the public health community – not least of all the Food Labelling Directive currently awaiting final Council adoption (Commission, 2008) – the Platform has become a permanent and effective feature of the nutrition policy landscape. Anti-tobacco policy, on the other hand, represents one of the most controversial and contradictory elements of the EU's policy portfolio. Whilst the Health Strategy commits the Commission to '...use the full potential of its instruments to combat tobacco consumption' (Commission, 2007a: 16), in a patent failure to apply the Health in All Policies (HiAP) mainstreaming principle (European Council, 1999), it continues to subsidise the production of tobacco through the Common Agricultural Policy (CAP) (EPHA, 27 July 2005). Furthermore, whilst the Diet Platform has succeeded in providing a forum in which the food industry feels comfortable participating in open dialogue, the ongoing battle between the public health community (and their counterparts in the EU institutions) and the tobacco industry has become '...something of a European health theme' (Randall, 2001: 99).

Soft law in the EU Health Strategy

Why then is there such a dramatic variation in the way soft law is used and the resulting outcomes, even within a single objective of the Health Strategy? Broadly speaking, soft mechanisms are seen to be more successful in the first two targets, namely cancer and organ donation/transplantation, whilst results have been far less consistent in the second two target areas. Two main differences can be identified as possible explanations for this contradiction. Firstly, the disparity in the configuration of actor preferences must be considered. The cancer and organ donation/transplantation fields face no obvious opposing body – most actors are in favour of reducing cancer rates and improving the safety and efficiency of human organ transplantation. The community of actors working against tobacco, alcohol and food consumption, on the other hand, face significant opposition from lobbies representing manufacturers, producers, advertisers, retailers and even citizens (Duina and Kurzer, 2004). Agreement on the common goal to be reached makes the implementation of both hard and soft law easier to achieve, whilst battles between industry lobbies and civil society stall this process and often work to the advantage of commercial interests. Secondly, cancer and organ donation/transplantation policies are far better suited for the sharing of information and the

exchange of best practice. Procedures in these areas are relatively standard throughout those member states which perform them successfully, making best practice easy to identify and implement across the rest of the EU. Conversely, consumption of tobacco, alcohol and food, incidence and causes of mental health problems, and lifestyle choices of the young and the elderly are all highly dependent upon the socio-economic culture of any given member state. Even where best practices can be identified, the cultural sensitivities involved make universal implementation of such practice near impossible to achieve.

Soft Europeanisation of health policy

A review of the mechanisms which currently constitute European health policy demonstrates the central role played by soft law. Given the limited legal competence provided for in Article 168 TFEU, a decline in the use of hard law measures through top-down Europeanisation is unsurprising. However, the volume of EU activity in health is considerable, and what *is* surprising is the 'softness' of the resulting horizontal, circular and bottom-up dynamics of Europeanisation. Even those hard law measures which reflect the direct competences provided for in the treaties can be shown, in most instances, to have been preceded by or supplemented with soft law instruments.

The EU Health Strategy provides a clear illustration of the 'soft Europeanisation' of health policy in the EU and the varying levels of success encountered through such mechanisms. The Health in All Policies (HiAP) case presents a soft variant of the traditional top-down dynamic, in that member states are compelled by EU action to accommodate health concerns into all policy areas. Since the White Paper states that the HiAP principle is applicable to all levels of government – European, national and regional – it can also be argued to exhibit multi-level dynamics. However, when considering the enforcement of the HiAP mechanism, an inherent weakness of soft law is revealed. As noted above, top-down Europeanisation requires an element of pressure to encourage compliance with EU measures – where soft law is concerned, advocates claim that 'naming and shaming' practices fulfil this role. However, the HiAP case demonstrates that, at the EU-level, this pressure is not always sufficient when faced with conflicts of interest.

Objective one of the Strategy highlights the debate concerning Europeanisation as an outcome or a process (see arguments made by Österdahl, 2004 and Jacobsson, 2004). Where Europeanisation is defined as the achievement of the goal of political unification, its aim is to harmonise the policies of the member states. Here, the role of soft law is often limited to that of precursor, paving the way for hard legislation. This seems to have been the case in organ transplantation policy, where soft law has been a specific step on the path to final policy integration. This in turn raises questions about the efficiency of soft mechanisms – as a precursor, soft law successfully fulfilled its role here, but does the consequent move to the directive indicate that soft law cannot, as opponents claim, play any given part as effectively as hard law? Conversely, the majority of others targets in objective one support the concept of Europeanisation as a process of national adaption and employ soft mechanisms to generate

shared learning, common nomenclature and dialogue between stakeholders. In cancer policy these processes are certainly considered to be as important as the outcomes they generate, subsequently being modelled across other issue areas, whilst for the more sensitive targets, soft policy is likely to be the only kind of common policy that can be achieved, and so constitutes an end in itself.

Soft law is clearly more effective in some areas than others. But what dictates the success or failure of a given instrument? Observers have noted several key characteristics. Firstly, the vast majority of studies highlight the importance of a default penalty. Greer and Vanhercke (2010: 222) state that,

> ...experimental governance will be most powerful when there is an unattractive 'default penalty'...The history of health care policy clearly has such a feature – the penalty for lack of action is progressive submission to internal market law as extended in an unpredictable, case-by-case manner.

Another key factor in the effectiveness of soft law instruments is the scope for expansive interpretation of the EU's legal competences in a given policy area. In evaluating the role of soft law in the healthy ageing objective of the Health Strategy, Randall notes that cancer policy, along with HIV/AIDS and drug dependence policy, became the subject of a campaign which required 'liberal interpretations' of the powers conferred by the treaties (Randall, 2001: 96) – EU action in older and younger persons health could also be seen as a stretching of legal competency, teetering as it does on the edge of the public health sphere. In evaluating the conditions necessary for soft law to be effective, Hervey and McHale (2004: 81; 335) describe the need for a perceived 'added value' in EU action. In areas such as cancer policy, organ donation and transplantation, the EU has consistently pursued a strategy of promoting the benefits to be gained and economies of scale involved in governing such issues at the European level. Where the benefits of conducting policy-making at the EU-level outweigh national concerns soft law, with its additional preservation of national autonomy, is likely to be the preferred governance framework of member states.

As well as demonstrating the factors and characteristics which make a given policy area amenable to soft law instruments, the case studies examined above highlight some of the weaknesses inherent in a softer governance approach. One of the most frequently identified problems is the practical difficulty involved in quantifying and measuring soft law mechanisms. Effectiveness is made difficult to determine by the long-term, gradual nature of soft law – with no given end point or concrete goal to use as a bench mark, measurement and evaluation of progress and success can be near impossible (Jacobsson, 2004: 99). More generally, Trubek and Trubek (2005: 356) argue that measurement based on the direct and visible impact of soft law mechanisms on national policy are fruitless, since '...the idea that all EU legislation creates hard and fast uniform rules that are easily enforced and will bring about a change is a chimera that flies in the face of the record'. Even in hard law areas, the root cause and catalyst of Europeanisation is difficult to pin down to one specific factor – the nature of soft law instruments merely exacerbates this problem.

Perhaps what is most clearly illustrated in the case study is the flexibility of soft law measures. Whilst they are far from uniformly effective, they are rarely inapplicable, since they suffer far less from the constraints of political resistance than hard law measures. They are most frequently invoked in horizontal, learning-transfer and bottom-up, institution-building conceptions of Europeanisation. The former is the dominant model of healthcare policy development, since it resists unwanted binding interference in an area of national competence, whilst the latter is the primary model of policy development in public health, where a clear added-value can be seen. Soft law's viability as a stand-alone policy instrument is arguably weaker than that of hard law, but as part of a hybrid-system, or as a second-choice alternative to formal legislation, soft measures have proven to be a useful agent of incremental Europeanisation.

Conclusion – soft Europeanisation and the future of EU health policy

Despite the absence of formal legal competence, EU involvement in health policy has expanded considerably over the last two decades. A portion of this expansion can be attributed to pressures from the Single Market, but this more acutely affects health services and healthcare policy, where top-down Europeanisation allows for the implementation of hard law across national health systems. This corresponds to the institution-building process of direct adaption pressure envisaged by Radaelli (2003a) and Börzel and Risse (2012). In public health, it is the steady proliferation of soft law instruments which has gently but consistently pushed the boundaries of EU involvement in member states' health systems, prompting Europeanisation as a process of learning and adaption, rather than institution-building. In this sense, it can be seen as closer to the horizontal and circular mechanisms described by Radaelli (2003a), generating indirect pressures for adaption at the national level via non-binding instruments. As described above, the processes involved in individual policy areas are much more differentiated than this but, generally speaking, soft law is increasingly being used across the public health sphere, either on its own or alongside hard law and financial incentives, to encourage common approaches (Hervey and McHale, 2004: 141; 244). Szyszczak (2006: 487) describes soft law and the new modes of governance (NMGs) as '...part of the inherent ability of the EU integration process to constantly reinvent itself as part of an evolutionary process of political and economic survival'. But what are its prospects in the further integration of this fledgling policy area?

As the case study shows, there is dramatic variation in the way soft law is employed and the outcomes it produces. It works more effectively in those areas where actors pursue common interests without major opposition, where cultural sensitivities are low and where best practices can be easily identified, shared and implemented. That is not to say, however, that soft law is sufficient for the integration or Europeanisation of a policy area – as the case study shows, some supplementary element of hard law is almost always necessary.

For many, the answer lies in the potential of hybrid policy models (Trubek *et al.*, 2005: 3). The emergence of soft law as the sole policy-making process of EU health policy is fairly

unlikely, but Hervey and Vanhercke (2010: 87) note that '...law and soft modes of health governance are becoming increasingly interwoven, thereby opening the door for hybrid EU policy instruments'. Such instruments are already explicitly employed in environment and fiscal policy and most EU policies are now characterised as 'mixed type', involving both hard and soft elements and demonstrating hierarchical, horizontal and round-about dynamics of Europeanisation (Trubek and Trubek, 2005: 362; Trubek *et al*., 2005: 5; Lenschow, 2011:67). Hybrid channels avoid some of the pitfalls of pure-soft law instruments by taking the best of both approaches and combining mutual learning and collective discourse with hard sanctions and democratic legitimacy where necessary. It is for this reason that Trubek and Trubek (2005: 344) discourage the discussion of the hard law versus soft law debate in either/or terms, since it deters exploration of hybrid governance models. As the organ donation and transplantation case shows, even successful soft law mechanisms can benefit from or require supplementary hard law instruments.

Turning to the implications of soft-law Europeanisation on the nature of the policy-making process, one of the primary arguments made by those who oppose soft law is its lack of democratic accountability. For those hybridity advocates who consider soft law as complementary to the traditional Community Method, this is not an obstacle to its use (Frykman and Mörth, 2004: 168). It might even be argued that it is precisely *because* it is not a democratic process, and is able to circumvent the political stumbling blocks that would otherwise be involved, that soft law has been so effective. However, since its main participants are unelected officials and both its content and form are often extremely vague, those who fear its use in place of hard law consider it a backwards step in the search for true democratic governance. Eberlein and Kerwer (2004: 126) refute the claim that soft law represents a more participatory, bottom-up form of policy-making, asserting that the process is dominated by the top or centre levels, more often than not by the Commission rather than the member states or civil society actors. A 2007 report by the European Parliament (2007: Point N) on the use of soft law in EU governance lamented the almost complete absence of a Parliament or Council role in the process and expressed concern that:

> Where the Community has legislative competence but the political will seems to be lacking to introduce legislation, use of soft law is liable to circumvent the influence of the other (democratic) instruments, may flout the principles of democracy and legality and may result in the Commission's acting *ultra vires*.

The report concluded that '...soft law all too often constitutes an ambiguous and ineffective instrument which is liable to have a detrimental effect on Community legislation and institutional balance and should be used with caution, even where it is provided for in the Treaty' (European Parliament, 2007: Point 1). This point serves to emphasise a broader issue identified in the literature on soft law. Radaelli (2003a), in particular, highlights an endemic tension within the NMGs in general, whose aim is to promote convergence and coordination at the highest political levels, but at the same time encourage diversity and competition. This inherent contradiction, Radaelli (2003a: 8) asserts, makes politicisation of soft law mechanisms inevitable.

It is unlikely that soft law will emerge as the sole governance approach of European health policy, but it is certain to play a commanding role in the development of this relatively young and uniquely complex sector. The political sensitivities, pressures from the internal market and member state resistance which characterises health makes hard law difficult to justify and even harder to implement. This has prompted a paradigm shift to a view of Europeanisation as a softer process of national adaption achieved through social learning and sharing of best practice. Soft law provides an avenue for EU involvement which preserves the autonomy of national governments whilst placing the protection of citizens' health high on the EU agenda. The next question raised by this trend is to what extent soft law can be characterised as a 'political wedge' rather than a neutral tool. As soft instruments proliferate and their delimiting effect upon national health policies is amplified, concern among policy-makers may also start to grow – it is at this point that the future of soft law as an avenue for EU involvement in health will be determined.

Bibliography

Birt, Christopher. 2008. “Response to 'The European Health Strategy – so what next?,” European Journal of Public Health 18 (6): 556-7.

Börzel, Tanja. 2001. “Pace-setting, foot-dragging and fence-sitting: Member state responses to Europeanisation,” Paper prepared for the ECSA conference, Madison (USA), May 31 – June 2, 2001.

Börzel, Tanja and Risse, Thomas. 2012. “When Europeanisation meets diffusion: Exploring new territory,” West European Politics 35 (1): 192-207.

Boyle, Peter, d’Onofrio, Alberto, Maisonneuve, Patrick, Severi, Gianluca, Robertson, Chris, Tubiana, Maurice and Veronesi, Umberto. 2003. “Measuring progress against cancer in Europe: has the 15% decline targeted for 2000 come about?,” Annals of Oncology 14: 1312-1325.

Buller, Jim and Gamble, Andrew. 2002. “Conceptualising Europeanisation,” Public Policy and Administration 17 (2): 4-24.

Bulmer, Simon. 2007. Theorizing Europeanisation. In Paolo Graziano and Maarten P. Vink, eds., Europeanisation – New Research Agendas, pp.46-58. Basingstoke: Palgrave Macmillan.

Bulmer, Simon and Burch, Martin. 1998. “Organising for Europe: Whitehall, the British States and the European Union,” Public Administration 76 (4): 601-628.

Bulmer, Simon and Burch, Martin. 2001. “The Europeanisation of central government: The UK and Germany in historical institutionalist perspective” in Gerald Schneider and Mark Aspinwall, eds., The rules of integration: Institutionalist approaches to the study of Europe, pp. 73-100. Manchester: Manchester University Press.

Cini, Michelle. 2001. “The Soft Law Approach: Commission rule-making in the EU's state aid regime,” Journal of European Public Policy 8 (2): 192-207.

Cram, Laura. 1997. Policy-making in the European Union: Conceptual Lenses and the Integration Process. Oxon: Routledge.

Diet Platform of the EU
http://ec.europa.eu/health/nutrition_physical_activity/platform/index_en.htm. Accessed August 2, 2011.

Di Robilant, Anna. 2006. “Genealogies of Soft Law,” American Journal of Comparative Law 54: 499-555.

Duina, Francesco and Kurzer, Paulette. 2004. “Smoke in your eyes: the struggle over tobacco control in the European Union,” Journal of European Public Policy 11 (1): 57-77.

Eberlein, Burkard and Kerwer, Dieter. 2004. “New Governance in the European Union: A Theoretical Perspective,” Journal of Common Market Studies 42 (1): 121-142.

EUROCHIP European Cancer Health Indicator Project http://www.tumori.net/eurochip. Accessed August 2, 2011.

European Commission Health Legislation Summary http://ec.europa.eu/health/legislation/policy/other_legislation/index_en.htm. Accessed June 5, 2011.

European Commission. 2004. "EU Commission Reflection Process," http://ec.europa.eu/health/ph_overview/Documents/byrne_reflection_en.pdf. Accessed June 19, 2011.

European Commission. 2005. "Commission Communication 'Healthier, safer and more confident citizens: a Health and Consumer protection strategy'," COM(2005) 115 final.

European Commission. 2006. "Public Consultation on EU Health Strategy," http://ec.europa.eu/health/ph_overview/Documents/strategy_discussion_en.pdf. Accessed June 19, 2011.

European Commission. 2007a. "Commission Staff Working Document accompanying the White Paper 'Together for Health: A Strategic Approach for the EU 2008-2013'," SEC(2007) 1376.

European Commission. 2007b. "Organ donation and transplantation: Policy actions at EU level," COM(2007) 275 final 30 May 2007.

European Commission. 2007c. "Commission Green Paper 'Towards a European free from tobacco smoke: policy options at the EU level'," COM(2007) 27 final 30 January 2007.

European Commission. 2007d. "Summary of Health Strategy Impact Assessment," http://ec.europa.eu/health/ph_overview/Documents/strategy_sum_impact_en.pdf Accessed June 19, 2011.

European Commission. 2007e. "White Paper 'Together for Health: A Strategic Approach for the EU 2008-2013'," COM(2007) 630 final.

European Commission. 2008. "Proposal for a regulation on the provision of food information to consumers," COM(2008) 40 final 30 January 2008.

European Commission. 2008a. "Communication on Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States," COM(2008) 819/3 8 December 2008.

European Commission. 2010a. "Commission Healthy Ageing Workshops," http://ec.europa.eu/health/ageing/events/ev_20101011_en.htm. Accessed August 2, 2011.

European Commission. 2010b. "Diet Platform Annual Report 2010".

European Council. 1999. “Council Resolution of 18 November 1999 on ensuring health protection in all Community policies and activities,” Official Journal 2000/C 86/02, 24/03/2000.

European Council. 2003. “Council Recommendation on cancer screening,” Official Journal L327/34, 16.12.2003.

European Council. 2010. “Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation”.

European Parliament. 2007. “Draft Report on Institutional and Legal Implications of the use of 'Soft Law' Instruments,” 2007/2028 (INI).

EPAAC “European Partnership for Action Against Cancer,” http://www.epaac.eu. Accessed August 2, 2011.

European Public Health Alliance (EPHA). Article of 19 October 2004. “EPHA responds to the Commission consultation on Health Strategy,” http://www.epha.org/a/1481. Accessed June 12, 2011.

European Public Health Alliance (EPHA). Article of 27 July 2005. “A critique of EU subsidies for tobacco farmers” http://www.epha.org/a/1078. Accessed August 2, 2011.

Faulkner, Gerda, Treib, Oliver, Hartlapp, Miriam and Leiber, Simone. 2005. Complying with Europe: EU harmonisation and soft law in the member states, Cambridge: Cambridge University Press.

Frykman, Henrik and Mörth, Ulrike. 2004. “Soft Law and Three Notions of Democracy: The Case of the EU,” in Ulrike Mörth, ed., Soft Law in Governance and Regulation: An Interdisciplinary Analysis, pp. 155-79. Cheltenham: Edward Elgar.

Greer, Scott. 2008. “Choosing paths in European Union health services policy: a political analysis of a critical juncture,” Journal of European Social Policy 18 (3): 219-231.

Greer, Scott and Vanhercke, Bart. 2010. “The Hard Politics of Soft Law: The Case of Health,” in Elias Mossialos, Govin Permanand, Rita Baeten and Tamara Hervey, ed., Health Systems Governance in Europe: The Role of European Union Law and Policy, Cambridge: Cambridge University Press.

Health-EU Youth Health. http://ec.europa.eu/health-eu/youth/index_en.htm. Accessed August 2, 2011.

Healthy Life Indicators. http://ec.europa.eu/health/indicators/healthy_life_years/index_en.htm. Accessed August 2, 2011.

Hervey, Tamara and McHale, Jean. 2004. Health Law and the European Union. Cambridge: Cambridge University Press.

Hervey, Tamara and Vanhercke, Bart. 2010. "Healthcare and the EU: the law and policy patchwork," in Elias Mossialos, Govin Permanand, Rita Baeten and Tamara Hervey, eds., Health Systems Governance in Europe: The Role of European Union Law and Policy, pp. 84-133. Cambridge: Cambridge University Press.

Jacobson, Harold. 2001. "Doing collaborative research in international legal topics: An autobiographical account," International Studies Review 3 (4): 15-23.

Jacobsson, Kerstin. 2004. "Between Deliberation and Discipline: Soft Governance in EU Employment Policy," in Ulrike Mörth, ed., Soft Law in Governance and Regulation: An Interdisciplinary Analysis. pp. 81-101. Cheltenham: Edward Elgar.

Ladrech, Robert. 1994. "Europeanisation of domestic politics and institutions: The case of France," Journal of Common Market Studies 32 (1): 69-89.

Leibfried, Stephan. 2010. "Social Policy: Left to the Judges and the Markets?," in Helen Wallace, Mark Pollack, and Alastair Young, eds., Policy-Making in the European Union 6th edition, pp. 253-82. Oxford: Oxford University Press.

Lenschow, Andrea. 2011. "Europeanisation of Public Policy," in Jeremy Richardson, ed., European Union: Power and Policy-Making 3rd edition, pp. 54-70. Oxon: Routledge.

López-Santana, Mariely. 2006. "The domestic implications of European soft law: framing and transmitting change in employment policy," Journal of European Public Policy 13 (4): 481-499.

Olsen, Johan. 2002. "The many faces of Europeanisation," Journal of Common Market Studies 40 (5): 921-952.

Österdahl, Inger. 2004. "The ECJ and Soft Law: Who's Afraid of the EU Fundamental Rights Charter?," in Ulrike Mörth, ed., Soft Law in Governance and Regulation: An Interdisciplinary Analysis. pp. 37-60. Cheltenham: Edward Elgar.

Radaelli, Claudio. 2003a. "The Open Method of Coordination: A New Governance Architecture for the EU?," Swedish Institute for European Policy Studies Report 2003:1 http://www.sieps.se/sites/default/files/3-20031.pdf. Accessed May 16, 2011.

Radaelli, Claudio. 2003b. "The Europeanisation of public policy," in Kevin Featherstone and Claudio Radaelli, eds., The Politics of Europeanisation, pp. 27-56. Oxford: Oxford University Press.

Randall, Ed. 2001. The European Union and Health Policy. Hampshire: Palgrave MacMillan.

Satori, Giovanni. 1970. "Concept Misformation in Comparative Politics," American Political Science Review LXIV(4): 1033-1053.

Senden, Linda. 2004. Soft Law in European Community Law. Oregon: Hart Publishing.

Snyder, Francis. 1993. "The Effectiveness of European Community Law: Institutions, Processes, Tools and Techniques," The Modern Law Review 56: 19-54.

Steffen, Monika, Lamping, Wolfram and Lehto, Juhani. 2005. "The Europeanisation of Health Policies," in Monika Steffen, ed., Health Governance in Europe: issues, challenges and theories, pp. 1-17. Oxon: Routledge.

Szyszczak, Erika. 2006. "Experimental Governance: The Open Method of Coordination," European Law Journal 12 (4): 486-502.

Toshkov, Dimiter. 2011. "Policy Making Beyond Political Ideology: The Adoption of Smoking Bans in Europe," Institute of Public Administration, Leiden University. http://www.dimiter.eu/articles/smoking%20bans%2029092011.pdf. Accessed June 11, 2012.

Trubek, David and Trubek, Lousie. 2005. "Hard and Soft Law in the Construction of Social Europe: the Role of the Open Method of Coordination," European Law Journal 11 (3): 343-364.

Trubek, David, Cottrell, Patrick and Nance, Mark. 2005. "Soft Law, Hard Law and European Integration: Toward a Theory of Hybridity," University of Wisconsin Madison Working Paper http://law.wisc.edu/facstaff/trubek/hybriditypaperapril2005.pdf. Accessed August 4, 2011.

Trubek, Louise, Nance, Mark and Hervey, Tamara. 2008. "Construction of a healthier Europe: Lessons from the fight against cancer," Wisconsin International Law Journal 26.

Versluis, Esther, van Keulen, Mendeltje and Stephenson, Paul. 2011. Analysing the European Policy Process. Hampshire: Palgrave Macmillan.

World Health Organisation Framework Convention on Tobacco Control (WHO FCTC) http://www.who.int/fctc/en. Accessed August 2, 2011.