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## *Public health policies*

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### 1. Introduction

This chapter considers how the European Union (EU) has discharged its obligations to develop and implement public health policy, obligations that arise primarily from its competences granted by Article 152 EC and Article 95 EC on the creation of the EU's internal market.

In doing so, the EU confronts four important tensions. The first concerns the relationship between those matters that are national and those that are international. Throughout history, threats to public health have transcended national borders, initially in the form of infectious diseases and more recently in the form of trade in dangerous goods, such as tobacco. Yet, reflecting the absence of an appropriate international architecture, responses have largely been developed and implemented at a national level. This only began to change in the latter part of the nineteenth century, when a series of international sanitary conferences began a process that would, in time, lead to the creation of the World Health Organization. However, even now, international public health remains a state-based model, involving interactions among state-defined actors, albeit through institutions established in international law.<sup>1</sup>

The nub of this tension is that the EU is neither an international public health organization nor a state. The EU lacks the public health expertise, resources and experience of international bodies such as the World Health Organization, the World Bank or UNICEF. It also lacks the capacity – in particular, the financial and human resources – of a state, which would enable it to deliver public health policies. Neither a state nor an ordinary international organization, the EU is often termed a 'supranational' body. However, 'supranational public

<sup>1</sup> K. Lee, K. Buse and S. Fustukian, *Health policy in a globalising world* (Cambridge: Cambridge University Press, 2002), p. 5.

health' is not a developed or recognized concept. How, then, does the EU respond to the requirement to develop public health policy? As we will see through the case studies discussed in this chapter, in some respects the EU acts, or attempts to act, as if it were an international public health organization. In other respects, the EU acts, or attempts to act, as if it were a state. Overall, it is not possible to discern a distinctive all-encompassing 'supranational' public health model that would apply to the EU. Rather, what emerges is a series of partially connected EU laws and policies that have various effects on public health.

A second tension concerns the concept of subsidiarity.<sup>2</sup> The EC Treaty has established a set of obligations for the EU institutions concerning the protection and promotion of public health but also makes clear that the organization and delivery of health care services is the responsibility of the Member States and not of the EU.<sup>3</sup> Yet, while public health and health care are discrete policy domains in EU law, in practice they are inextricably interlinked. Public health measures can reduce the burden of disease falling on health care systems, exemplified by the spectacular fall in smoking-related diseases in many countries in the past decade, while health promotion is a core function of a health care system. In practical terms, this can make it difficult to ascertain what is or is not within the scope of EU law.

The third tension is between the imperative to promote public health and the consequences of the EU's own legal system, especially those elements designed to create the internal market, within which the 'factors of production' move freely. Free trade within the internal market is the keystone of the EU's legal order, on which the processes of European integration rely. Supreme and directly effective provisions of EU (internal market) law make it possible for restrictions on free movement of goods and people within the EU to be challenged before national courts.<sup>4</sup> Yet, from its inception, it was recognized that

<sup>2</sup> See Article 5(2) EC: '[i]n areas which do not fall within its exclusive competence, the Community shall take action, in accordance with the principle of subsidiarity, only if and insofar as the objectives of the proposed action cannot be sufficiently achieved by the Member States, and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community'.

<sup>3</sup> Article 152(5) EC.

<sup>4</sup> See Chapter 2 in this volume.

the free trade on which the then European Economic Community was built would inevitably have to incorporate measures to address public health risks.

Microorganisms have taken advantage of trade routes from the earliest days, exemplified by the spread throughout Europe of the Black Death in 1348. Throughout history, the speed with which an infectious disease epidemic spread was limited only by the means of transport available at the time. Horses and sailing ships have given way to aircraft, so that, as the outbreak of SARS in 2002 showed, infections can now traverse the globe in a few hours. From at least the time of the Venetian Republic, which introduced the system known as quarantine, whereby ships would wait outside ports for forty days to ensure they were free from disease,<sup>5</sup> governments have struggled to balance the benefits of free trade against the risks of epidemics. In the EU, this balancing act takes place within laws on the internal market. But, as we will see, the EU has also used its explicit public health competences to develop elements of public health policy that cut across the four freedoms.

The fourth tension arises from the situation within the European Commission whereby one Directorate-General (the Directorate-General for Health and Consumer Protection (DG SANCO)) has a specific responsibility for public health, but many policies that might be considered to be directly relevant to public health are located elsewhere, often reflecting other priorities and underpinned by different values. For example, although drug dependence was the only one of the 'major health scourges' to be specified in Article 129 of the Treaty of Maastricht, EU policy on illicit drugs has been developed within its policy on 'freedom, security and justice'.<sup>6</sup>

Although the creation of a separate Directorate-General with responsibility for public health was, in part, a response to the Commission's failure to ensure food safety following the emergence of bovine spongiform encephalopathy (BSE), responsibility for food safety now resides with the European Food Safety Agency in Parma.

Health and safety, which also might be expected to fall within the remit of a Directorate-General with responsibility for health, is instead covered by the Directorate-General for Employment, Social

<sup>5</sup> L. O. Gostin, *Public health law: power, duty, restraint* (Berkeley: University of California Press, 2000).

<sup>6</sup> EC Treaty, Title IV.

Affairs and Equal Opportunities (DG Social Affairs), with extensive involvement by the European Agency for Health and Safety at Work, located in Bilbao, and the European Foundation for the Improvement of Living and Working Conditions, located in Dublin.

Moreover, the EU has a long-standing environmental policy, with a significant body of environmental law involving matters such as air and water quality, waste disposal and noise pollution,<sup>7</sup> all of which have direct consequences for public health and yet are under the auspices of the Directorate-General for Environment, Nuclear Safety and Civil Protection (DG Environment).

Public health research, of which the European Union is now a major funder, is the responsibility of the Directorate-General for Science, Research and Development (DG Research), while consistent Europe-wide information on health and its determinants is collected by EUROSTAT.<sup>8</sup> Responsibility for the European Union's borders, a vital defence against smuggling of narcotics and tobacco, resides with the Directorate-General for Justice, Freedom and Security (DG Justice).

The EU's Common Agricultural Policy exerts a major influence on the diet – and thus on the health – of Europeans,<sup>9</sup> encouraging the consumption of meat and dairy products rather than fruit and vegetables as a result of incentives developed initially when the problem facing Europe was one of possible starvation rather than oversupply. Yet even though the share of the European workforce engaged in agriculture is a fraction of what it once was, agricultural policy remains focused on meeting the needs of providers rather than consumers, under the leadership of the Directorate-General for Agriculture and Rural Development (DG Agriculture).

<sup>7</sup> See, for instance, Council Directive 96/62/EC on ambient air quality assessment and management, OJ 1996 No. L296/1; European Parliament and Council Directive 2000/60/EC establishing a framework for Community action in the field of water policy, OJ 2000 No. L327/1; European Parliament and Council Directive 2006/12/EC on waste, OJ 2006 No. L114/1; European Parliament and Council Directive 2002/49/EC relating to the assessment and management of environmental noise, OJ 2002 No. L189/1.

<sup>8</sup> M. McKee and J. Ryan, 'Monitoring health in Europe: opportunities, challenges and progress', *European Journal of Public Health* 13 (2003), Supp: 1–4.

<sup>9</sup> Faculty of Public Health, *A CAP on health: the impact of the EU Common Agricultural Policy on public health* (London: Faculty of Public Health, 2007).

The provisions of the internal market also exert a major influence on public health, not only in relation to tobacco, which is discussed in detail below, but through influencing the trade in other products that impact on health. For example, internal market regulations forced Finland, when it joined the EU, to dismantle elements of its state alcohol monopoly and, not long afterwards, following Estonia's accession, it reduced domestic prices as a consequence of its inability to block imports of cheap drinks from nearby Estonia. As predicted, there has been a steep rise in deaths from alcohol-related disorders.<sup>10</sup> Thus, as even this brief overview shows, responsibility for the factors that influence the health of Europe's population is dispersed widely within the Commission.

Given the scope of public health at the level of the EU, it is necessary to be selective. This chapter begins by setting out the legal framework for the EU's competence in public health, discussing the Treaty provisions and the regulations governing the EU's public health programmes. It then examines the challenges faced by the EU in developing public health policy through two case studies: communicable diseases and tobacco. The case studies reflect a range of different types of EU activity, including both 'hard law' and 'soft law' responses, as well as the development of EU-level policies in these fields. The two examples selected also represent areas of significant political and social impact, where the EU's involvement has enjoyed a relatively high profile. The chapter concludes with a summary of the key interactions between EU law and policy in the area of public health, and some thoughts on its future trajectory.

## 2. The EU's competence in public health

### A. *The Treaty*

Although Article 100A(3) of the 1987 Single European Act required the Commission when taking harmonizing measures to take as a base for its proposals a high level of health protection, it was not until the Treaty of Maastricht entered into force in 1993 that the EU had

<sup>10</sup> A. Koski, R. Sirén, E. Vuori and K. Poikolainen, 'Alcohol tax cuts and increase in alcohol-positive sudden deaths: a time-series intervention analysis', *Addiction* 102 (2007), 362–8.

explicit competence in the field of public health. Amendments to the EC Treaty in the Maastricht Treaty, Articles 3(o) and 129, stipulated that the Community should contribute to the attainment of a high level of health protection and identified two areas for Community action: disease prevention and health protection. This stipulation was strengthened in the 1997 Amsterdam Treaty through Article 152 EC. Article 152(1) EC requires the EU to ‘mainstream’ health protection, by ‘ensur[ing] a high level of human health protection’ in all its policies and activities. This confers upon the Commission – and, specifically, DG SANCO – a responsibility to ensure that this is the case, implying a duty to conduct health impact assessments of EU policies. However, DG SANCO’s capacity to do so is extremely limited and commentators have noted how some EU policies clearly do not ensure a high level of human health protection, most notably subsidies for tobacco production,<sup>11</sup> which will only be phased out by 2010.

The EU’s action complements national policies. It must ‘be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health’. It must tackle ‘the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education’. In 1999, when the Treaty of Amsterdam entered into force, this part of Article 152 EC was significantly expanded from the Maastricht mandate, in response to the BSE crisis.<sup>12</sup>

Article 152(2) sets out the division of powers between the Member States and the EU institutions in the field of public health. Member States are obliged to coordinate their public health policies and programmes, in liaison with the Commission. The provision makes it clear that, in accordance with the principle of subsidiarity, the main responsibility for public health remains firmly with the Member States. This is emphasized by sub-paragraph 5, which provides that ‘Community action in the field of public health shall fully respect the responsibilities of the Member States for the organization and

<sup>11</sup> L. Joossens and M. Raw, ‘Are tobacco subsidies a misuse of public funds?’, *British Medical Journal* 30 (1996), 832–5.

<sup>12</sup> T. Hervey, ‘The legal basis of European Community public health policy’, in M. McKee, E. Mossialos and R. Baeten (eds.), *The impact of EU law on health care systems* (Brussels: PIE-Peter Lang, 2002); T. Hervey and J. McHale, *Health law and the European Union* (Cambridge: Cambridge University Press, 2004).

delivery of health services and medical care'. Presumably, the main concern of the Member States in agreeing this part of Article 152 was the preservation of national competence over the financing of national health systems, a matter of ongoing (at the time of writing) debate within and beyond the Commission.<sup>13</sup>

Article 152(4) sets out the procedures by which the EU institutions may act in the health field, and delimits the types of measures that may be enacted. Two types of legislation are envisaged: 'measures' and 'incentive measures'. The 'incentive measures' of Article 152(4)(c) are the basis for the various European Commission-funded public health programmes, discussed below. In addition, the EU institutions may adopt binding regulatory measures on the safety of human blood and organs and public health measures in the veterinary and phytosanitary fields. Some of these provisions, especially those in Article 152(4)(b), are not an extension of Community competence, as they refer to areas of well-established EU policy – in particular, the Common Agricultural Policy. Their specific inclusion in Article 152 is apparently due to failings such as those exposed by the BSE crisis.<sup>14</sup> Significantly, a different legislative procedure (co-decision, which involves the European Parliament and qualified majority voting in the Council, rather than the old procedure of Article 37 EC) is to be used for such measures that are directly concerned with protecting public health.<sup>15</sup> However, the worldwide ban on sales of British beef in 1996, and thus prior to the Treaty of Amsterdam, was imposed by the Commission on the basis of a directive enacted under Article 43 of the Treaty, which allows it to take immediate action where there is a risk to human or animal health.<sup>16</sup>

Other provisions in Article 152(4)(a) are more obviously an extension of the power of the EU institutions. Their presence in the Treaty

<sup>13</sup> D. Cohen, 'EU residents may be able to travel to any member state for care from 2010', *British Medical Journal* 335 (2007), 1115.

<sup>14</sup> A. P. Van der Mei and L. Waddington, 'Public health and the Treaty of Amsterdam', *European Journal of Health Law* 5 (1998), 129–54.

<sup>15</sup> Although the Council is to act by qualified majority under Article 37 EC, the role of the European Parliament is consultative only, in contrast to the co-decision role envisaged in Article 152 EC.

<sup>16</sup> Council Directive 90/425/EEC concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market, OJ 1990 No. L224/29; M. McKee and E. Steyger, 'When can the European Union restrict trade on grounds of public health?', *Journal of Public Health Medicine* 19 (1997), 85–6.

may be explained by various health scandals concerning blood and human organs, such as the distribution and transfusion of HIV-infected blood and blood products.<sup>17</sup> It may also be relevant that an embryonic 'market' in human blood, organs and other substances is emerging in the EU. Using ordinary internal market law to regulate this 'market' is politically and ethically sensitive in many Member States, as these substances are neither conceptualized as 'goods' nor the object of ordinary commerce or consumption. However, 'consumers' of these 'goods' do need to be protected within the EU's legal framework. Article 152 EC gives power to the Council to enact the necessary protective regulations as public health measures. Such measures may be modelled on existing consumer protection regulation based on internal market provisions, in which EU law sets only a 'minimum floor' of regulatory protection and Member States are free to enact higher standards if they wish. Again, the subsidiarity principle is invoked, with a specific exclusion in sub-paragraph 5 for 'national provisions on the donation or medical use of organs and blood'. This refers to the significant differences in the Member States' legal systems concerning donor consent.<sup>18</sup>

Article 152(4)(a) has been used as the legal basis for the Blood Safety Directive,<sup>19</sup> which provides that only duly accredited, authorized or licensed national blood establishments may collect and test human blood, and sets various inspection requirements and quality control systems with respect to such establishments. It is also the legal basis for the Human Tissue Directive,<sup>20</sup> which requires Member States to establish a regulatory framework for the 'donation, procurement, testing, processing, preservation, storage and distribution of human

<sup>17</sup> H. Roscam Abbing, 'Human tissue and consumer protection from a European perspective', *European Journal of Health Law* 2 (1995), 298–304; Van der Mei and Waddington, 'Public health', above n.14; J. Abraham and G. Lewis, *Regulating medicines in Europe: competition, expertise, and public health* (London: Routledge, 2000).

<sup>18</sup> Roscam Abbing, 'Human tissue', above n.17.

<sup>19</sup> The 'Blood Safety' Directive, European Parliament and Council Directive 2002/98/EC on setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC, OJ 2003 No. L33/30.

<sup>20</sup> European Parliament and Council Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, OJ 2004 No. L102/48.

tissues and cells intended for human applications and of manufactured products derived from human tissues and cells intended for human applications'.<sup>21</sup> This Directive applies to all human tissues and cells, including haematopoietic peripheral blood, umbilical-cord and bone-marrow stem cells, reproductive cells (eggs, sperm), foetal tissues and cells and adult and embryonic stem cells. However, it excludes from its scope of application those tissues and cells that are used as an autologous<sup>22</sup> graft in the same surgical procedure, blood and blood products (these are already covered by the Blood Safety Directive), and 'organs, or parts of organs if their function is to be used for the same person as the entire organ on or in the human body'.<sup>23</sup>

What is perhaps most significant about Article 152 EC is that it gathers together powers and activities of the EU institutions in the public health field in a much more coherent and logical manner than in the pre-1999 Treaty provisions. If one considered the Treaty texts alone, one might conclude that the EU can now be said to have its own public health policy, which interacts with those at the national level in the Member States, albeit one that is somewhat more modest than in areas such as environmental policy. To some extent, the details of that policy are a matter for elaboration among the institutions of the European Union. In this respect, therefore, the EU can be said to be acting more like a state than a conventional international organization in the development of its public health policy.

The Treaty of Lisbon does envisage the further 'mainstreaming' of public health, with a new Article 9 TFEU,<sup>24</sup> which reiterates the obligation on the EU to take into account 'protection of human health' in defining and implementing its other policies. Although this provision was already present in the EC Treaty post-Maastricht, its position in the post-Lisbon Treaties suggests greater legal weight. Yet the Europeanization of public health is far from complete, and is unlikely ever to be so given the significant constraints on EU competence that

<sup>21</sup> Article 2(1), Directive 2004/23/EC, above n.20.

<sup>22</sup> This means 'cells or tissues removed from and applied back to the same person'. Article 3(q), Directive 2004/23/EC, above n.20.

<sup>23</sup> Article 2(2)(c), Directive 2004/23/EC, above n.20.

<sup>24</sup> Under the Lisbon Treaty amendments, the EC and EU Treaties are replaced by the Treaty on European Union and Treaty on the Functioning of the European Union (TFEU).

are embedded in the pre-Lisbon EC Treaty and repeated in other provisions of the Treaty of Lisbon,<sup>25</sup> as well as the practical reality of there being political opposition to transferring further responsibility for public health policy to the EU level.

### *B. The public health programmes*

Article 152 provided the legal basis for the first EU-level integrated public health framework programme. Before 2003, the EU had adopted a range of smaller programmes in various high profile public health areas, such as ‘Europe against Cancer’<sup>26</sup> and ‘Europe against AIDS’.<sup>27</sup> In each case, they were the result of exceptional circumstances. Thus, Europe against Cancer, initiated in 1987, arose from a proposal by President François Mitterrand of France (advised by Professor Maurice Tubiana) and Prime Minister Bettino Craxi of Italy (advised by Professor Umberto Varonese), shortly after the former had been diagnosed with prostate cancer.<sup>28</sup> The establishment of a programme to combat cancer, even if it involved stretching the scope of European law, set an important precedent when the AIDS epidemic emerged.

The Amsterdam revisions gave the Commission a new impetus and, in 1998, under the leadership of Commissioner David Byrne, the Commission launched a debate on a new direction for EU public health policy.<sup>29</sup> A fundamental revision was proposed, envisaging an integrated EU public health strategy with three strands:

<sup>25</sup> Under the amendments introduced by the Treaty of Lisbon, Article 152 EC is replaced by Article 168(7) TFEU. This elaborates the previous Article 152(5) EC to include the sentence: ‘[t]he responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them’.

<sup>26</sup> Resolution of Council and the Representatives of the Governments of the Member States on a programme of action of the European Communities against cancer, OJ 1986 No. C184/19.

<sup>27</sup> Decision of the Council and Ministers of Health for the Member States 91/317/EEC adopting a plan of action in the framework of the 1991 to 1993 ‘Europe against AIDS’ programme, OJ 1991 No. L175/26.

<sup>28</sup> A. Gilmore and M. McKee, ‘Tobacco policy in the European Union’, in E. A. Feldman and R. Bayer (eds.), *Unfiltered: conflicts over tobacco policy and public health* (Cambridge, MA: Harvard University Press, 2004), p. 394.

<sup>29</sup> European Commission, ‘Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on the development of public health policy in the European Community’, COM (98) 230 final, 15 April 1998.

- improving information for the development of health
- reacting rapidly to threats to health
- tackling health determinants through health promotion and disease prevention.

The basic principles underpinning this proposed strategy remain in place today and concentrate on a limited number of priorities: to emphasize the improvement of health; to be sufficiently flexible to respond to new developments; and to be credible and convincing from the point of view of the citizens of the EU.

The first Public Health Framework Programme (2003–8) was based on those three priorities, which were set out as the programme's general objectives in Article 2 of its enabling instrument, Council and Parliament Decision 1786/2002/EC.<sup>30</sup> Each general objective was to be pursued by 'actions' from among those listed in the Annex of the Decision, organized by reference to the three general objectives of Article 2 of the Decision. The detail here reflects topical concerns of the health systems of the Member States at the time, at least those related to 'public' health elements on disease prevention and health promotion. For instance, 'rapid reaction to health threats' includes exchange of information on strategies to counter health threats from physical, chemical or biological sources in emergency situations, including those relating to terrorist acts.<sup>31</sup> Other examples include developing strategies for reducing antibiotic resistance, implementing strategies on life-style related health determinants, and exchanging information on genetic determinants of health and the use of genetic screening.

The 'actions' are implemented by EU-level support for 'activities', in cooperation with the Member States. 'Activities' may implement all or part of an action, and may be combined. The complex arrangement of 'objectives', 'actions' and 'activities' reflects a compromise position between those legislative actors who wished to place more constraints on the funding of the EU public health programme and those who valued flexibility. Broadly speaking, the European Parliament sought greater flexibility, while the Council sought to impose constraints on

<sup>30</sup> European Parliament and Council Decision 1786/2002/EC adopting a programme of Community action in the field of public health (2003–2008) – Commission Statements, OJ 2002 No. L271/1.

<sup>31</sup> Decision 1786/2002/EC, above n.30, Annex, 2.4.

the disbursement of EU finances for the public health programme. 'Activities' fall into four categories, related to:

- monitoring and rapid reaction systems
- health determinants
- legislation
- consultation, knowledge and information.

The last category includes matters such as developing and maintaining networks for exchange of information on best practice in public health and the effectiveness of health policies.<sup>32</sup> Since 1 January 2005, the implementation of the public health programme has been carried out by an executive agency, on behalf of the Commission.<sup>33</sup>

DG SANCO, under the leadership of Markos Kyprianou, Commissioner from 2004, commenced negotiations on the second Public Health Programme (though the word 'public' has now disappeared from its title) in April 2005.<sup>34</sup> The Commission's bold proposal aimed to merge 'public health' and 'consumer protection' into one joint programme, and the text of the proposal tied this explicitly to 'what citizens want'.<sup>35</sup> The Commission proposed three core objectives for the programme. The programme would:

[P]rotect citizens from risks and threats which are beyond the control of individuals, and that cannot be effectively tackled by individual Member States alone; increase the ability of citizens to take better decisions about

<sup>32</sup> Article 3(d)(v), Decision 1786/2002/EC, above n.30.

<sup>33</sup> Commission Decision setting up an executive agency, the 'Executive Agency for the Public Health Programme', for the management of Community action in the field of public health – pursuant to Council Regulation 58/2003/EC, OJ 2004 No. L369/73. The Executive Agency for the Public Health Programme has now been renamed the Executive Agency for Health and Consumers, see Commission Decision 2008/544/EC of 18 June 2008 amending Decision 2006/415/EC concerning certain protection measures in relation to highly pathogenic avian influenza of the subtype H5N1 in poultry in the Community, OJ 2008 No. L173/27. See also <http://ec.europa.eu/eahc/index.html>; and Chapter 4 in this volume.

<sup>34</sup> European Commission, 'Proposal for a European Parliament and Council Decision establishing a programme of Community action in the field of health and consumer protection 2007–13', COM (2005) 115 final, 6 April 2005.

<sup>35</sup> 'EU citizens want to live healthily and safely wherever and whoever they are and to have confidence in the products and services they consume. They also want a say in the decisions that affect their health and consumer interests. The EU, national and regional authorities, businesses and civil society must play a part to respond to these concerns, but there are common health and consumer policy challenges that only EU level action can tackle.' *Ibid.*, 2.

their health and consumer interests; and it would mainstream health and consumer policy objectives across all Community policies in order to put health and consumer issues at the centre of policy-making.

Had these objectives, especially the third, been adopted, there would have been a marked change from the first Public Health Programme, giving DG SANCO a position within broader EU policy-making that it does not currently enjoy. The objectives were to be met by six 'strands' of the programme: the existing three of health information, health threats and health determinants, and three new ones – response to threats, disease prevention and cooperation between health systems. The proposed financial framework was €1203 million.

The integration of health and consumer protection did not survive long. The Conference of Presidents<sup>36</sup> decided on 30 June 2005 to split the proposal into two programmes.<sup>37</sup> The European Parliament proposed eight objectives for the health programme. These included improving efficiency and effectiveness in health systems, tackling health inequality and empowering citizens by facilitating patient mobility and increasing transparency between the various countries' health systems, all of which would again have suggested a significant change of focus from the current programme. The latter objective arose from the activity of various EU institutions and actors<sup>38</sup> following the *Kohll* litigation on free movement of patients.<sup>39</sup> The Parliament proposed a budget – solely for the health programme strand and excluding the consumer protection elements of the original proposal – of €1500 million.

Following the inter-institutional agreement on the EU's future financial framework for 2007–13,<sup>40</sup> in May 2006 the Commission amended

<sup>36</sup> The Conference of Presidents consists of the President of the European Parliament and the chairpersons of the political groups within Parliament. It is responsible, *inter alia*, for relations between the European Parliament and other EU institutions.

<sup>37</sup> Draft European Parliament legislative resolution on the proposal for a European Parliament and Council Decision on a programme of Community action in the field of health and consumer protection (2007–2013) – health aspects, OJ 2006 No. C291E/372.

<sup>38</sup> Such as the High Level Group on Health Care and Medical Systems.

<sup>39</sup> T. Hervey, 'The European Union and the governance of health care', in G. de Búrca and J. Scott (eds.), *New governance and constitutionalism in Europe and the US* (Oxford, Portland: Hart, 2006), pp. 179–210.

<sup>40</sup> Interinstitutional Agreement between the European Parliament, the Council and the Commission on budgetary discipline and sound financial management – Declarations, OJ 2006 No. C139/1.

its original proposal, taking account of the new reality that, by virtue of the new financial settlement, the budget available for health was about one third of that originally envisaged. The Commission accordingly focused its proposal more tightly, around three objectives:

- improving citizens' health security
- promoting health for prosperity and solidarity
- generating and disseminating health knowledge.

The proposed budget was €365.6 million. The Commission added new foci on health inequalities, promoting healthy ageing and addressing children's health and gender questions, some of which reflect the European Parliament's proposed amendments.<sup>41</sup> The Council reached political agreement (unanimously) on a common position<sup>42</sup> that endorsed this budget and these three objectives<sup>43</sup> in November 2006.

A few further changes were made at the Parliament's second reading, in July 2007.<sup>44</sup> By this stage, it was obvious that the programme could not begin until January 2008. Parliament sought to bring health inequalities further to the fore, by including this explicitly within the second objective, which then read 'to promote health, including in the

<sup>41</sup> European Commission, 'Communication from the Commission pursuant to the second subparagraph of Article 251(2) of the EC Treaty concerning the common position of the Council on the adoption of a European Parliament and Council Decision establishing a second Programme of Community action in the field of Health (2007–2013)', COM (2007) 150 final, 23 March 2007.

<sup>42</sup> European Council, 'Common position adopted by the Council with a view to the adoption of a European Parliament and Council Decision establishing a second programme of Community action in the field of health (2007–13)', 16369/06, Interinstitutional File 2005/0042 A (COD).

<sup>43</sup> Article 2, Decision 1786/2002/EC, above n.30: '1. The Programme shall complement, support and add value to the policies of the Member States and contribute to increased solidarity and prosperity in the European Union by protecting and promoting human health and safety and improving public health. 2. The objectives to be pursued through the actions set out in the Annex shall be:

- to improve citizens' health security,
- to promote health,
- to generate and disseminate health information and knowledge.

The actions referred to in the first subparagraph shall, where appropriate, support the prevention of major diseases and contribute to reducing their incidence as well as the morbidity and mortality caused by them.'

<sup>44</sup> European Parliament Resolution on the Council common position for adopting a European Parliament and Council Decision establishing a

### Box 5.1 Resources available under the Public Health Programme 2008–13

Operational Objective 1: Citizen's Health Security – €97.572 million

- Action 1: protect citizens against health threats – €65.048 million.
- Action 2: improve citizen's safety – €32.524 million.

Operational Objective 2: Promote Health – €113.834 million

- Action 1: foster healthy, active ageing and help bridge inequalities – €42.281 million.
- Action 2: promote healthier ways of living by tackling health determinants – €71.553 million.

Operational Objective 3: Generate and Disseminate Health Knowledge – €113.82 million

- Action 1: exchange knowledge and best practice – €48.78 million.
- Action 2: collect, analyse and disseminate health information – €65.04 million.

reduction of health inequalities'. The financial envelope was reduced to reflect the reduction in running time of the programme to €321.5 million. Both of these changes are reflected in the final legislative text.<sup>45</sup>

The EU's first Public Health Programme attracted considerable interest. Many more applications for funding were received than the available funding could support, with applications from all Member States. The EU was able to fund some projects under all the 'actions' and 'activities' envisaged.<sup>46</sup> However, it is not easy to assess the overall impact of the programme, as it lacked specific goals against

second programme of Community action in the field of health (2008–2013), 16369/2/2006 – C6–0100/2007 – 2005/0042A(COD).

<sup>45</sup> European Parliament and Council Decision 1350/2007/EC establishing a second programme of Community action in the field of health (2008–13), OJ 2007 No. L301/3.

<sup>46</sup> W. J. Oortwijn *et al.*, *Interim evaluation of the public health programme 2003–2008* (Santa Monica: RAND Corporation, 2007), pp. 100–1.

which its success (as opposed to that of individual projects) could be measured. Moreover, as we have seen, priorities for the EU's public health programmes are determined within the EU's normal legislative processes. There are many criteria that can inform the process of priority setting in public health, based on considerations such as the contribution to the burden of disease, the cost-effectiveness of intervention or the magnitude of future risk. The extent to which such considerations have informed the development of the EU's public health programmes – and thus what they seek to achieve – is unclear.

Concerns have been voiced about the emphasis placed on different types of projects within the public health programme. A focus on 'innovation' may mean that relatively simple pilot projects tend to be favoured over longer term or more complex activities. The competitive tendering process and the need to put together EU-wide partnerships and to secure co-funding mean that applications are likely to be conservative rather than ground-breaking. The same can be said for the selection of projects for funding. It is not always clear what the criterion of 'EU added value' means in practice.

The extent to which the results of projects are subsequently embedded into national practices is also unclear. The lack of any requirement for a 'legacy plan' in applications means that opportunities may be missed to ensure that the benefits of successful activities will be sustained into the future. Neither is it clear how the results of the public health programme can be fed into EU law and policy-making where this might be appropriate.

There is little evidence of horizontal coordination between the Public Health Programme and other Commission activities. An independent report<sup>47</sup> found strained relationships with the Directorates-General for Employment and Social Affairs; Environment, Nuclear Safety and Civil Protection; Regional Policy; and Development, although it did find good relationships with DG Research. In some cases (the Directorate-General for Competition, DG MARKT), it seems that relationships may be virtually non-existent. Finally, although the Commission has established working relationships with WHO and the Organisation for Economic Co-operation and Development (OECD) (as well as other international organizations), these relationships also pose problems of coordination, perhaps because the programme's

<sup>47</sup> *Ibid.*, pp. 106–7.

complexity makes the multiple relationships involved impossible to manage in practice.

Yet, as already noted, the EU's Public Health Programme represents only one of the means by which the EU fulfils its obligation to improve public health, prevent human illness and diseases, and obviate sources of danger to human health.<sup>48</sup> In order to illuminate some of the others, this chapter now turns to examine in more detail how all of these developments impact on one of the key areas of public health: the control of communicable disease.

### 3. The detection and control of communicable diseases

The primary legal framework on communicable disease control within which the EU and its Member States operate is governed by international law and, specifically, the International Health Regulations. These originated in the International Sanitary Regulations, agreed by governments meeting in Paris in 1851. In due course, responsibility for the Regulations passed to the World Health Organization, which, in 1969, consolidated and updated them, creating the International Health Regulations (IHR). By the end of the twentieth century, it was apparent that they had failed to keep pace with changing circumstances. Specifically, they focused on a limited number of diseases (plague, yellow fever, cholera and, initially, smallpox, until it was eradicated), they depended on timely and accurate notification by government (despite growing evidence that some governments suppressed information to protect tourism and other economic interests), and they failed to address the need for rapid transmission of information. The 2005 revision of the regulations addresses all of these concerns. Instead of verified cases of the three diseases, states are required to notify WHO of any 'public health emergency of international concern'.<sup>49</sup> This is an event that constitutes a risk to other states and that may require a coordinated international response. Criteria for notification include the seriousness of the event, how unusual it is, the potential to spread internationally and the possibility that restrictions on trade or travel may result. The IHR encompass not only communicable diseases but also

<sup>48</sup> Article 152(1) EC.

<sup>49</sup> World Health Organization, *International Health Regulations* (Geneva: WHO, 2005).

toxic and other hazardous exposures. Linked to the implementation of the IHR, a Global Outbreak Alert and Response Network has been established, with its secretariat based within WHO. It links a number of other networks, including the Global Public Health Intelligence Network, a web crawler that monitors emerging evidence suggestive of disease outbreaks. As with the earlier Regulations, governments are limited in the actions they may take to impede trade and travel. Any action that 'significantly interfere(s)' with international traffic, defined as refusing it or delaying it for 24 hours, must be justified on scientific grounds, as must any medical checks on potential travellers.

The revised IHR came into force on 15 June 2007 and 194 states are parties to them. They allow WHO to make recommendations, including restrictions on travel and trade, but they incorporate no enforcement mechanism. There is, instead, a dispute resolution procedure. Prior to the coming into force of the IHR, it was possible for governments to register reservations. No EU Member State did so.

The EU itself is not a party to the IHR,<sup>50</sup> but all of its Member States are. Although the Commission claims that some matters within the IHR are matters of exclusive Community competence,<sup>51</sup> an alternative interpretation is that these are matters of shared competence between the EU and its Member States.<sup>52</sup> Article 57 of the IHR requires that '[s]tates parties that are members of a regional economic integration organization shall apply in their mutual relations common rules in force in that regional economic integration organization'. Thus, should WHO recommend a restriction on trade or travel, the EU would have to act collectively, following an initiative from the Commission. The European Commission has published a communication setting out the interrelationships between the IHRs and EU law and has proposed a series of working practices, with a 'memorandum of understanding' to clarify relationships and to ensure coordinated responses.<sup>53</sup> Consequently, the remainder of this section

<sup>50</sup> This reflects the EU's constrained competence in the field of health.

<sup>51</sup> For example, Article 26 of the International Health Regulations, above n.49, on protection of personal data. See European Commission, 'International health regulations', COM (2006) 552 final, 26 September 2006, on the International Health Regulations.

<sup>52</sup> See Article 4 TFEU, to enter into force if the Treaty of Lisbon is ratified by all the Member States.

<sup>53</sup> European Commission, 'International Health Regulations', above n.49.

should be interpreted in the light of the Member States' international obligations under the IHR.

The progressive dismantling of borders within Europe – most recently, the expansion of the border-free 'Schengen area' to include twenty-eight states<sup>54</sup> – with the resultant increase in mobility of people and goods, has greatly increased the opportunity for the spread of infectious diseases. There are, however, various safeguards in the Treaties that have been developed in subsequent legislation. In particular, although outside the scope of this chapter, there is an extensive body of law linked to monitoring and compliance mechanisms to ensure the safety of agricultural products.<sup>55</sup> Here, discussion will be confined to the basic principles determining when a Member State can act to restrict the movement of goods and people on the grounds of public health.

#### A. *Restrictions on movements of goods*

Articles 28 and 29 EC prohibit any quantitative restrictions on imports and exports between Member States, *or any measures having equivalent effect*. The meaning of 'equivalent effect' was established in *Dassonville*,<sup>56</sup> which stated that '[a]ll trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade are to be considered as measures having an equivalent effect to quantitative restrictions'. The key point is the focus on the effect of the measure, and not its intention. However, Article 30 EC does make provision for prohibitions or restrictions on imports, exports or goods in transit justified on grounds of 'public morality, public policy or public security; the protection of health and life of humans, animals or plants ... Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.'

The interpretation of these provisions follows from the *Cassis de Dijon* case,<sup>57</sup> which addressed the refusal by German authorities, on grounds of public health, to allow the sale of a French liqueur on the

<sup>54</sup> Belgium, France, Germany, Italy, Luxembourg, the Netherlands, Denmark, Greece, Portugal, Spain, Austria, Finland, Sweden, Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, Slovenia, Bulgaria, Romania, Iceland, Norway and Switzerland.

<sup>55</sup> R. O'Rourke, *European food law* (London: Sweet and Maxwell, 2005).

<sup>56</sup> Case C-8/74, *Procureur du Roi v. Dassonville* [1974] ECR 837.

<sup>57</sup> Case 120/78, *Cassis de Dijon* [1979] ECR 649.

basis of its alcohol content. The European Court of Justice ruled, first, that there was a presumption that a good lawfully marketed in one Member State should be admitted into any other Member State without restriction and, second, if a restriction was imposed to achieve a legitimate public health goal, it must be proportionate to the goal it pursues and it must use the least restrictive means to achieve it. For example, a restriction on imports would not be permitted if safety could be assured by enhanced labelling.<sup>58</sup> Consequently, the principle of proportionality is now accepted as applying to actions affecting the fundamental freedoms by the EU and by Member States. Such actions must be suitable and necessary to achieve the desired end and must not impose a burden on the individual that is excessive in relation to the objective to be achieved.

The Court has been willing to permit restrictions not only where there is a clear case for action, but also where there is genuine doubt about the risk to health. This was apparent when it upheld the decision by authorities in the Netherlands to ban the import of processed cheeses containing nisin, even though other countries believed it to be safe.<sup>59</sup> In contrast, it has rejected restrictions viewed primarily as obstacles to trade, even when they might possibly be justified on grounds of public health. An example was its rejection of a British ban on poultry imports just before Christmas in 1981,<sup>60</sup> ostensibly because of a fear of importing Newcastle disease, but viewed by many as an attempt to stop imports of French turkeys and to protect the British turkey market.

### *B. Restrictions on movements of people*

The Treaties also make provision for restrictions on the movement of people between Member States on grounds of public health, although the circumstances in which this may be done are extremely limited. The earliest European legislation setting out the basis for restricting movement was Directive 64/221/EEC,<sup>61</sup> which covered individuals suffering from certain conditions. These included the diseases specified in the International Health Regulations, active or latent

<sup>58</sup> *Ibid.*

<sup>59</sup> Case 53/80, *Koninklijke Kassfabriek Eyssen BV* [1981] ECR 409.

<sup>60</sup> Case 40/82, *Commission v. United Kingdom (Turkeys)* [1982] ECR 2793.

<sup>61</sup> Council Directive 64/221/EEC on the co-ordination of special measures concerning the movement and residence of foreign nationals which are

tuberculosis, syphilis, and other infectious or contagious parasitic diseases if they were subject to provisions that applied to nationals in the country concerned. They also included certain diseases and disabilities 'which might threaten public policy or public security'. These were drug addiction and profound mental disturbance.

Directive 64/221/EEC has since been repealed by Directive 2004/38/EC.<sup>62</sup> This substantially narrows the conditions that may lead to restrictions to those considered by WHO to have epidemic potential or where restrictions are also being applied to citizens of the Member State concerned. Furthermore, action to remove someone so affected cannot be taken if they have been in the country for over three months.

### C. A European surveillance and response system

Formal legal powers to inhibit the movement of goods or people are, of course, only one element of a comprehensive response to communicable disease. As noted above, the 1992 Treaty of Maastricht gave the EU not only power, but also responsibility, to act in the field of public health. What is now Article 152 EC provided the legal basis for the EU's subsequent actions in establishing proactive mechanisms to combat communicable disease.

Since the early 1990s, the European Commission had supported the development of various networks linking national authorities responsible for communicable disease surveillance and control. These were very successful and there are numerous examples of outbreaks that were only detected because of effective communication within the networks. For instance, the linking of outbreaks of *Legionella* infection across Europe back to a resort where individuals from various Member States were staying, but who only became ill when they returned to their home country, enabled identification of the source of the infection in circumstances where only a few cases might be detected in a particular country, and thus the source would not

justified on grounds of public policy, public security or public health, OJ 1964 No. 56/850

<sup>62</sup> European Parliament and Council Directive 2004/38/EC on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States amending Regulation 1612/68/EEC and repealing Directives 64/221/EEC, 68/360/EEC, 72/194/EEC, 73/148/EEC, 75/34/EEC, 75/35/EEC, 90/364/EEC, 90/365/EEC and 93/96/EEC, OJ 2004 No. L158/77.

otherwise have been found.<sup>63</sup> In other cases, serotyping allowed what would otherwise seem like isolated episodes of food-borne infection to be traced to a factory supplying small quantities of products across Europe. Yet this system was far from perfect. The networks depended to a large extent on the enthusiasm of committed individuals. Geographical coverage was often extremely patchy. There was no sustainable funding and networks had to rebid for resources regularly, with no certainty that the work they were doing would be seen as important.

An evaluation of Europe's ability to respond to outbreaks that crossed borders was undertaken in 1999.<sup>64</sup> It reviewed a series of outbreaks involving meningococcal disease, salmonella and shigella food poisoning, legionella, and influenza, and found numerous problems. International surveillance is critically dependent on well-functioning national systems, but, in some Member States, these were extremely weak. Even when outbreaks were detected, they were sometimes not notified to neighbouring countries. The study of influenza revealed a low level of preparedness in several Member States. Funding for investigations of outbreaks was often extremely fragile and it was often impossible to identify resources in the short time scales involved. One outbreak investigation that was studied required the coordination of funds from seven different sources. There was a particular problem when resources were required to conduct investigations in third countries. Communication mechanisms were often weak, exemplified by failures to transmit information on outbreaks of *Legionella* infection to the travel industry. Finally, there were few opportunities for shared learning between national authorities and others.

This evaluation strengthened the case for change. At the time, the prevailing political climate was unfavourable to the creation of a new European institution. Consequently, there was a broad consensus that the way forward was to build on, but strengthen, the existing networks (see Box 5.2). However, the discovery of anthrax in postal packages in the United States in 2001 and the emergence

<sup>63</sup> C. Joseph *et al.*, 'An international investigation of an outbreak of Legionnaires disease among UK and French tourists', *European Journal of Epidemiology* 12 (1996), 215–9.

<sup>64</sup> L. MacLehose *et al.*, 'Communicable disease outbreaks involving more than one country: systems approach to evaluating the response', *British Medical Journal* 323 (2001), 861–3.

of severe acute respiratory syndrome (SARS) in south-east Asia in 2002 – events with profound implications for state security and the economy, respectively – led to a rethink. In 2004, the EU established a new European Centre for Disease Prevention and Control (ECDC).<sup>65</sup> Based in Stockholm, the ECDC is designed to provide a structured, systematic response to the threat from communicable diseases and other serious health threats in Europe. It complements but does not replace existing national centres for disease control and European networks. Its main tasks, and some examples of how it undertakes them, are as follows:

- Surveillance: ECDC supports epidemiological surveillance activities at the European level. This involves actions by the ECDC itself, by the various networks or by national centres of excellence. ECDC coordinates the work of the European Disease Surveillance Networks.
- Scientific advice: ECDC convenes expert groups drawing on its EU-wide networks and ad hoc scientific panels.
- Identification of emerging health threats (‘epidemic intelligence’): a web-based notification system provides the means for 24-hour access to specialists in communicable diseases and dissemination of information in real time to Member States. Responsibility for action remains with Member States and the Commission.
- Training: the European Programme for Intervention Epidemiology Training (EPIET) has made a major contribution to training communicable disease epidemiologists in Europe. It enables epidemiologists to undergo training at a national public health institute in another Member State.
- Health communications: ECDC publishes *Eurosurveillance*, a bulletin on disease surveillance and prevention circulated rapidly within the European public health community.
- Providing technical assistance: ECDC supports networks of reference laboratories, taking measures to enhance their quality and expertise. It has a rapid reaction capacity that extends beyond the EU. It can also support the Commission in the area of humanitarian aid and assistance in responding to outbreaks in developing countries.

<sup>65</sup> European Parliament and Council Regulation 851/2004/EC establishing a European Centre for disease prevention and control, OJ 2004 No. L142/1.

### Box 5.2 European networks involved in surveillance and control of communicable diseases<sup>66</sup>

#### General surveillance

BSN Basic Surveillance Network

#### Sexually transmitted/blood-borne diseases

Euro-HIV European Centre for the Epidemiological Monitoring of AIDS

ESSTI European Surveillance of Sexually Transmitted Infections

#### Vaccine preventable diseases

ESEN European Seroepidemiology Network

ELWGD European Laboratory Working Group on Diphtheria

EUVAC-NET Surveillance Community Network for Vaccine Preventable Infectious Diseases

EU IBIS European Union Invasive Bacterial Infections Surveillance

#### Zoonoses/food-borne diseases

Internet International Surveillance Network for the Enteric Infections Salmonella and VTEC

DIVINE-NET Prevention of emerging (food-borne) enteric viral infections: diagnosis, viability testing, networking and epidemiology

#### Respiratory diseases

Euro-TB European Surveillance of Tuberculosis

EISS European Influenza Surveillance Scheme

<sup>66</sup> R. Reintjes, 'International and European responses to the threat of communicable disease', in R. Coker, R. Atun and M. McKee (eds.), *Health systems and the challenge of communicable disease: experiences from Europe and Latin America* (Buckingham: McGraw Hill, 2008), pp. 141–53.

**Box 5.2 (cont.)**

EWGLINet	European Working Group for Legionella Infections
<b>Antibiotic resistance/nosocomial infections</b>	
EARSS	European Antimicrobial Resistance Surveillance Consumption
ESAC	European Surveillance of Antimicrobial Consumption
HELICS	Hospitals in Europe Link for Infection Control through Surveillance
Others	
ENIVD	European Network for Imported Viral Diseases
EUNID	European Network of Infectious Diseases Physicians

The ECDC has been moving forward on many fronts. Several networks have been integrated into the ECDC's activities, such as the European Influenza Surveillance Scheme (EISS), the Early Warning and Response System (EWRS) and the European Centre for the Epidemiological Monitoring of AIDS (EuroHIV). In April 2008, it increased consistency with WHO reporting requirements.<sup>67</sup> The ECDC is also working to strengthen links with the broader public health community, including by hosting a meeting with twenty-one European scientific societies representing a wide range of disciplines related to public health in February 2007, which was designed to facilitate networking and collaboration. In June 2007, it presented the first comprehensive report on communicable disease in the EU.<sup>68</sup>

The ECDC has achieved a great deal in a very short time, but now stands at a crossroads. Its role is very limited compared with,

<sup>67</sup> Commission Decision 2008/351/EC amending Decision 2000/57/EC as regards events to be reported within the early warning and response system for the prevention and control of communicable diseases, OJ 2008 No. L117/40.

<sup>68</sup> A. Amato-Gauci and A. Ammon, 'Annual epidemiological report on communicable diseases in Europe', Report on the status of communicable diseases in the EU and EEA/EFTA countries, Stockholm, European Centre for Disease Prevention and Control (2007).

for example, the American Centers for Disease Control, and its relationships with national surveillance authorities are not fully defined. An external evaluation published in summer 2008 identified potential for ECDC to extend its work into other health threats that cross borders, including environmental pollution, its involvement in health surveillance, especially in the area of non-communicable disease, supporting national systems where these are weak, and facilitating consistent definitions and reporting mechanisms, or development of benchmarks for national disease surveillance systems. However, it proposed that no decision be taken until 2013. A recent study analysing seven European surveillance systems suggested that such benchmarks could be an effective tool for comparing systems and identifying priorities for improvement.<sup>69</sup>

#### *D. Communicable diseases: a summary*

In summary, the provisions of EU law and policy discussed in this section show how the EU has navigated the tension between the free movement implied by internal market law and the potential threats to public health arising from the greater ease with which communicable diseases might spread within a single European market. Public health protection can no longer serve as a guise for national trade protectionism. International health regulations provide a neutral basis for genuinely necessary restrictions on free movement.

The EU response to the control of communicable disease has evolved rapidly since 2000. At its centre is the ECDC, which has grown quickly to become a major international player. The legal basis in the Treaty has been used to develop a secure institutional infrastructure at the EU level, and to sustain EU funding for communicable disease control. In these respects, the EU is acting increasingly like a state. However, the ECDC acts in partnership with national authorities, with whom it shares competences. Moreover, the EU does not sit at the same table as the states parties in the international public health organizations that negotiate key legal instruments such as the IHR.

<sup>69</sup> R. Reintjes *et al.*, 'Benchmarking national surveillance systems: a new tool for the comparison of communicable disease surveillance and control in Europe', *The European Journal of Public Health* 17 (2007), 375–80.

Instead, the EU tends to work alongside the international institutions, especially the WHO Regional Office for Europe.

We turn now to consider our second case study: the EU's control of tobacco. Again, we are interested in the roles of EU legislation, especially internal market law, alongside soft law, and also the use of EU-funded projects to create and disseminate information that is subsequently used in legislative processes to promote public health.

#### **4. Tobacco control**

For many years, the European Commission took almost no action to counter the health threat posed by tobacco. An attempt, under occupational health provisions, to include action against smoking in the 1983 Asbestos Directive<sup>70</sup> received little support from Member States, so that the most that could be achieved was a requirement to display 'no smoking' signs in work-places where asbestos was being used. Another opportunity to take action arose in 1985, during discussions on harmonizing excise duties. However, advice was obtained from a Dutch academic later discovered to be reporting to the tobacco firm Philip Morris, and little was achieved.

The establishment, in 1987, of the 'Europe against Cancer' programme (EACP) at last placed tobacco control firmly on the agenda. The EACP initially functioned as a relatively independent unit reporting directly to the Directorate-General of Social Affairs and was supported by an influential expert committee. Its first 'action plan to combat cancer' (1987–9)<sup>71</sup> identified tackling smoking as a priority and, in 1988, it began to develop legislative proposals. By the late 1980s, the introduction of qualified majority voting, coupled with new provisions in the Single European Act on health and safety (designed to balance some of the consequences of the internal market) made legislation possible. Between 1989 and 1992, seven directives and one non-binding resolution on tobacco were adopted. These measures represented a considerable improvement

<sup>70</sup> Council Directive 83/477/EEC on the protection of workers from the risks related to exposure to asbestos at work (second individual Directive within the meaning of Article 8 of Directive 80/1107/EEC), OJ 1983 No. L263/25.

<sup>71</sup> Council and Government Representatives of the Member States resolution on a programme of action of the European Communities against cancer, OJ 1986 No. C184/19.

on what had existed in some countries, such as the Netherlands and Greece, where there had been almost no tobacco-control legislation. Elsewhere, as in the United Kingdom, legislation supplanted ineffective voluntary agreements. The comparative EU-wide data generated by EACP assisted in marshalling sufficient support for legislation at the EU level.<sup>72</sup>

After 1992, although tobacco control remained on the agenda, the development of legislation appeared to slow, with new directives only enacted in the field of tobacco taxation throughout the rest of the 1990s (see Table 5.1). One reason was the tortuous negotiation of, and subsequent challenge to, the Advertising Directive, as detailed below. However, other factors also played a part. The Danish decision to reject the Maastricht Treaty, and evidence of waning support for the EU elsewhere, served to caution against expanding the scope of European legislation generally. The recently-introduced principle of subsidiarity also discouraged legislation.<sup>73</sup>

More specifically, while the Treaty of Maastricht did confer a public health competence on the EU, the creation of eight new public health programmes diverted attention from tobacco control. Simultaneously, internal disagreements within the Commission led, in 1992, to the EACP being subsumed within the Commission's public health unit and the role of its expert committee being undermined. Key staff left and the programme was left substantially weakened by what many saw as a deliberate ploy. This was compounded a few years later by the termination of the contract of the Bureau for Action on Smoking Prevention, which had supported the Commission's work on tobacco, perhaps because Commission staff felt that it was too vociferous in its calls for action.<sup>74</sup> This decision was supported by the Governments of Germany, the Netherlands and the United Kingdom,<sup>75</sup> as well as

<sup>72</sup> See L. Trubek, M. Nance and T. Hervey, 'The construction of a healthier Europe: lessons from the fight against cancer', 26 *Wisconsin International Law Journal* (2008) 804–43.

<sup>73</sup> L. Joossens, 'Comments on Commission report COM (95) 285 final, on the approximation of taxes on cigarettes', International Union Against Cancer, September 1996.

<sup>74</sup> L. Doyle, 'Brussels stubs out cash for anti-smoking group', *Guardian*, 10 October 1996.

<sup>75</sup> I. I. Gabara, 'Why the EU's tobacco policy is up in smoke', *Wall Street Journal Europe*, 10 October 1996.

Table 5.1. Major EU tobacco control directives<sup>76</sup>**Labelling and product regulation**

Labelling Directive 1989	89/622/EEC	Tar and nicotine yield to be printed on the side and health warnings on the front of each pack. Each warning to cover 4% of the appropriate surface, 6% for countries with two official languages and 8% for countries with three official languages.
Smokeless Tobacco Directive 1992	92/41/EEC	Amended Directive 89/662/EEC by introducing warnings for packaging of tobacco products other than cigarettes and banning the marketing of certain tobacco products for oral use.
Tar Yield Directive 1990	90/239/EEC	Sets a maximum tar yield of 15 mg per cigarette by 31 December 1992 and 12 mg per cigarette from 31 December 1997.
Tobacco Products Directive 2001 (replaces Directives 89/662/EEC, 92/41/EEC and 90/239/EEC)	2001/37/EC	Specifies a reduction in tar yield from 12 mg to 10 mg, sets nicotine and carbon monoxide limits, health warnings to cover 30% of the pack front, additive and ingredient disclosure, a ban on misleading product descriptors such as 'light' and 'mild'. Derogations on tar yield for Bulgaria until January 2011.

<sup>76</sup> Note that some of the earlier directives have been replaced by later directives, as indicated in the table.

Table 5.1. (*cont.*)

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**Taxation**

Tax Directives 1992, 1995, 1999 and 2002  (1999 and 2002 Directives amend earlier Directives)	92/78/EEC 92/79/EEC 92/80/EEC 95/59/EEC 99/81/EC  2002/10/EC	Set minimum levels of duty on cigarettes and tobacco.  Requires an overall excise duty (specific and ad valorem com- bined) of at least 57% of the final retail selling price of the price category most in demand, plus a VAT rate of 13.04%. Introduces a fixed minimum amount of taxation expressed in euros by requiring that the minimum excise rates outlined above shall be at least €64 per 1000 cigarettes for the price category most in demand.
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**Advertising and sponsorship**

Television Broadcasting Directive 1989 (amendments made by Directives 97/36/EC and 2007/65/EC in response to new technology)	89/552/EEC	Bans all forms of television broadcast and on-demand audiovisual media service advertising for tobacco products.
Tobacco Advertising and Sponsorship Directive 1998. Annulled October 2000	98/43/EC	A comprehensive ban on tobacco advertising and sponsorship.
Tobacco Advertising Directive	2003/33/EC	Bans cross-border sponsorship, advertising in printed publications, on the Internet and radio.

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the Agriculture Directorate-General,<sup>77</sup> all known to be sympathetic to tobacco producers.

An additional key factor restraining the adoption of further EU law from the mid-1990s was the development of the tobacco industry lobby. Although ever present, previous work<sup>78</sup> suggests that it was not until this point that the industry became seriously engaged in the European legislative scene. The Confederation of European Community Cigarette Manufacturers (CECCM), established in the late 1980s, assumed a greater lobbying role, working with national lobbyists to influence governments such as that of the United Kingdom, described as ‘a key ally of the tobacco industry in the European Community’.<sup>79</sup> As elsewhere, the industry used ‘favourable contacts’<sup>80</sup> to enhance its lobbying position. The Philip Morris Institute for Public Policy Research was established in 1993 as ‘a non-profit organisation which aims to stimulate debate by publishing discussion papers that address major policy issues confronting today’s European decision-makers’. Links were built with libertarian organizations throughout Europe, with employers (especially in the hospitality and advertising industries) and with trade unions (especially those representing tobacco workers and growers). Individuals on influential EC committees – such as the European Confederation of Employers and of Unions<sup>81</sup> and the European Trade Unions Confederation – were targeted assiduously.

In spite of these various obstacles, the EU has developed an array of legal measures concerning tobacco control. It has also played a key role in promoting tobacco-free life-styles, including the funding of two major media campaigns – the ‘Feel Free to Say No’ campaign (2001–4) and ‘HELP: For a Life without Tobacco’ (2005–8) – and has played a key role in the negotiation of WHO’s Framework Convention on Tobacco Control (FCTC). The following sections provide a brief review of these measures.

<sup>77</sup> R. Watson, ‘European antismoking group loses grant’, *British Medical Journal* 311 (1995), 10.

<sup>78</sup> Gilmore and McKee, ‘Tobacco policy’, above n.28, p. 394.

<sup>79</sup> D. Martin and D. B. Martin, ‘Why Philip Morris needs the United Kingdom’, Memorandum to Gerard Wirz, Philip Morris, Bates Nos. 2501207805–09 (1992).

<sup>80</sup> P. Morris, ‘Smoking restrictions 3-year plan’, Phillip Morris Corporate Affairs Europe (undated).

<sup>81</sup> *Ibid.*

It must be noted that since Article 129 (now 152) EC expressly excludes the ability to take harmonizing measures for public health purposes, all EU tobacco control directives (other than the Taxation Directives), have been enacted as internal market measures under Article 100a (now 95) EC. Measures adopted under Article 95 EC must be proportionate (i.e., they must not go further than necessary in achieving the aim of ensuring the smooth functioning of the internal market). This has left them open to challenge by the tobacco industry and its allies, who have now challenged all the major Tobacco Control Directives enacted since 1989, as described in detail below.<sup>82</sup>

### A. Advertising ban

Bans on tobacco advertising are a proven means of reducing smoking, a finding that is hardly surprising given the tobacco industry's willingness to spend many millions of euros promoting its products. Yet, for many years, the industry maintained the fiction that advertising was only undertaken to encourage people to switch brands.

In 1989, the European Union banned tobacco advertising on television. This ban was contained within a broader directive regulating trans-border television services, Directive 89/552/EEC.<sup>83</sup> The same year, a comprehensive advertising and sponsorship ban was proposed and, following amendment, was approved by the Parliament in 1992, in the face of concerted tobacco industry opposition. It then became stuck in the Council of Ministers for many years, with Germany, the Netherlands and the United Kingdom consistently blocking it. The German Government, during its Presidency in 1995, sought to introduce a weakened compromise proposal, now confirmed to have been developed by the industry,<sup>84</sup> but it failed to gain sufficient support. The crucial change was the election of a Labour Government

<sup>82</sup> ASPECT Consortium, *Tobacco or health in the European Union: past, present and future*, The ASPECT Report (Brussels: European Communities, 2004).

<sup>83</sup> Council Directive 89/552/EEC on the coordination of certain provisions laid down by Law, Regulation or Administrative Action in Member States concerning the pursuit of television broadcasting activities, OJ 1989 No. L298/23.

<sup>84</sup> M. Neuman, A. Bitton and S. Glantz, 'Tobacco industry strategies for influencing European Community tobacco advertising legislation', *Lancet* 359 (2002), 1323–30.

in the United Kingdom in 1997, with a manifesto commitment to reverse the stance of the outgoing Conservative Government, members of which had strong financial links with the tobacco industry. There was, however, a delay, as the new government was discovered to have weakened its support, allowing an exemption for Formula One motor racing, a move that coincided with the acceptance of a large donation from a leading figure in motor racing.<sup>85</sup> Denials of a link provoked wide-spread public disbelief. However, the new stance by the United Kingdom Government did make a compromise agreement possible, although Germany and Austria remained opposed. Soon afterwards, however, Germany and four British tobacco companies mounted a legal challenge, arguing that the new Directive 98/43/EC was illegal, violated several elements of the Treaty and was a misuse of the EU's legislative power.<sup>86</sup>

As explained above, in the absence of a legislative basis in public health, the Directive was enacted as an internal market measure under Article 95 EC on the basis that it intended to standardize the market in tobacco advertising across the EU. The industry claimed that, because the Directive's principal aim was public health protection, the EU was not competent to act, and the Directive was therefore a misuse of power. The Court, following its Advocate General, rejected this particular line of reasoning, but did rule against the Directive on the grounds that it was not properly enacted on the legal basis of Article 95 EC.<sup>87</sup> The Court accepted that obstacles to the free movement of goods and services could arise from differences between national laws on the advertising of tobacco products. In the case of press products, for instance, different restrictions in different Member States on the advertising of tobacco products in the printed press was likely to give rise to obstacles to the free movement of the printed media or advertising services. But this does not apply to all types of products in, on or through which tobacco products are advertised. To prohibit advertising tobacco on posters, parasols, ashtrays and so on, which do not cross borders,

<sup>85</sup> J. Warden, 'UK adheres to Formula One exemption', *British Medical Journal* 315 (1997), 1397–402.

<sup>86</sup> Case C-376/98, *Germany v. European Parliament and Council (Tobacco Advertising)* [2000] ECR I-8419; Joined Cases T-172/98 and T-175/98 to T-177/98, *Salamanca* [2000] ECR II-2487 (these latter cases were held to be inadmissible by the Court of First Instance).

<sup>87</sup> Case C-376/98, *Germany v. European Parliament*, above n.86, paras. 98–9, 101, 105, 111, 114, 116.

or in advertising spots in cinemas in no way facilitates trade in those products. Thus, the Directive exceeded its legal basis as an internal market measure because, instead of facilitating, or removing barriers to, trade, in the case of some advertising products, the Directive prohibited it altogether. This was disproportionate to what was needed to ensure the proper functioning of the internal market. The Court also noted that the Directive neither harmonized national rules nor removed distortions of competition, either in the market for tobacco *advertising* products or services, or in the market for tobacco products themselves. The Directive was therefore annulled by the Court. This result highlights the difficulty of enacting effective public health legislation in the absence of a specific legal basis within the EC Treaty. It illustrates the limitations on the EU's ability to determine 'state-like' public health policy, especially where a specific act of public health protection is politically contentious, and therefore cannot be easily justified as necessary within the imperatives of internal market law.

Following the Court's ruling, the Commission proposed a revised directive,<sup>88</sup> limited to measures that the Commission considered to be the minimum needed to achieve the proper functioning of the internal market. It was confined to cross-border advertising (in print media and on the radio and Internet) and sponsorship. It also excluded a ban on indirect advertising, which the Advocate General considered as having an unproven impact on consumption.<sup>89</sup> The new Directive on Tobacco Advertising entered into force in August 2005. A further attempt by the German Government to mount a legal challenge to it was unsuccessful.<sup>90</sup> The Court found that this new Directive did eliminate obstacles to trade in advertising products

<sup>88</sup> European Commission, 'Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products', COM (2001) 283 final, 30 May 2001. European Parliament and Council Directive 2003/33/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products, OJ 2003 No. L152/16.

<sup>89</sup> AG Opinion, Case C-376/98, *Germany v. European Parliament*, above n.86, paras. 159–63; F. Kling, 'Ban on tobacco advertising not legal', *Tobacco Journal International* 4 (2000), 58.

<sup>90</sup> Case C-380/03, *Germany v. European Parliament and Council* [2006] ECR I-11573.

and services. The Court also dismissed pleas that the Directive circumvented Article 152(4)(c) EC, that insufficient evidence of distortions to trade was given, procedural irregularities existed and there was a breach of proportionality.

While this new partial advertising ban, focused on cross-border issues, was being finalized, the Council issued a recommendation<sup>91</sup> concerning aspects of tobacco control that are considered to be the responsibility of Member States. This non-binding act recommended, *inter alia*, that Member States adopt measures to restrict methods of tobacco advertising that have no cross-border effects. The 2002 recommendation is an example of an instance in which the EU's competence to adopt hard law was limited, but the EU institutions turned to soft law. As such measures are not binding or enforceable in the courts, they may have little or no practical effect. However, such soft law can sometimes be a precursor to future hard law measures, when the legal and political climate allows.<sup>92</sup>

### B. Product regulation and labelling

In the late 1980s and early 1990s, the EU implemented a series of directives on labelling and tar yield, again based on the argument that the laws of Member States should be harmonized in order to ensure free trade.<sup>93</sup> Packs were required to display tar and nicotine yields, and include a small health warning. It soon became apparent that the industry was exploiting weaknesses in the legislation. Although Directive 89/622/EEC<sup>94</sup> stipulated that health warnings should be clearly legible and printed on a contrasting background,

<sup>91</sup> Council Recommendation on the prevention of smoking and on initiatives to improve tobacco control, OJ 2003 No. L22/31.

<sup>92</sup> An example in the health field is the 'Blood Safety' Directive, Directive 2002/98/EC, above n.19, which refers to a Commission communication and three Council resolutions in its preamble. For further examples, see L. Senden, *Soft law in European Community law* (Oxford: Hart, 2004).

<sup>93</sup> European Parliament and Council Directive 2001/37/EC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products, OJ 2001 No. L194/26.

<sup>94</sup> Council Directive 89/622/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products, OJ 1989 No. L359/1.

a 1993 evaluation revealed that most had gold lettering that, being reflective, offered only minimum contrast.<sup>95</sup> Furthermore, manufacturers were using additives to increase the addictive effect of nicotine and to make cigarettes more attractive to first-time users.<sup>96</sup> This led to moves to consolidate and strengthen existing legislation in the form of a new Tobacco Products Directive drafted in November 1999 and, after much negotiation, agreed in 2001.<sup>97</sup> The Directive: (a) reduced the maximum tar yield from 12 to 10 milligrams and established for the first time maximum nicotine and carbon monoxide yields; (b) specified an increase in the size (to 30% of the front and 40% of the back of cigarette packs for countries with one official language) and improvement in the specification of health warnings; (c) required the disclosure of ingredients and additives, along with reasons for their use and evidence of their safety; (d) established a ban on misleading product descriptions such as 'light' or 'mild'; and (e) specified a prohibition on the marketing of non-compliant tobacco products (in terms of maximum yields and descriptors) outside the EU, a manufacturing restriction that was described by the tobacco industry as a 'de facto export ban'.<sup>98</sup> In addition, Member States were enabled to use pictures and graphics as part of the health warnings.

The passage of the Directive was difficult. The industry and its trade union allies argued that it would lead to job losses in European manufacturing plants and queried its legal basis in light of the ruling of the Court on the Tobacco Advertising Directive. The Parliament, however, voted to strengthen the Directive, for example, by increasing the size of the health warnings, although the Council twice rejected most of these amendments.<sup>99</sup> The final result, due largely to the skill

<sup>95</sup> R. Watson, 'Europe gets tougher on tobacco', *British Medical Journal* 309 (1994), 1037–8.

<sup>96</sup> C. Bates, G. Connolly and M. Jarvis, *Tobacco additives: cigarette engineering and nicotine addiction* (London: Action on Smoking and Health, 1999).

<sup>97</sup> Directive 2001/37/EC, above n.93.

<sup>98</sup> M. Bevers, 'Rationale behind new strategy', *British American Tobacco*, Bates No. 325123195–325123196 (2000).

<sup>99</sup> European Parliament, 'Report on the proposal for a European Parliament and Council Directive on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products (recast version)', COM(1999) 594 – C5–0016/2000 – 1999/0244(COD); European Parliament, 'Recommendation

of the Parliament's rapporteur, was a compromise that went well beyond earlier legislation.

The Directive was, however, subject to a series of legal challenges by the industry, which, although centred on the validity of its legal basis in the Treaty, also invoked international agreements on trade-mark and intellectual property rights. The first case was lodged in 2000 by British American Tobacco (BAT) while the proposed Directive was proceeding through the EU legislative bodies. BAT filed an access case for Commission documents concerning preparatory work relating to the Directive proposal. This case was dismissed by the European Court of First Instance, which upheld the Commission's argument that it could not accede to an access request when the documents requested did not exist.<sup>100</sup> Within a few months of the Directive passing into EU law, British American Tobacco, Imperial Tobacco and Japan Tobacco International (JTI) initiated legal proceedings. They focused on the inadequacy of Article 95 as the legal basis of the Directive, claiming it was a public health measure being introduced as an internal market measure. Infringement of the principles of proportionality and subsidiarity were also cited.

In addition, the claimants maintained that the labelling provisions for yields and larger health warnings (Article 5 of the Directive) and the ban on misleading text (Article 7 of the Directive) would breach trade-mark and intellectual property rights (Article 295 EC, the fundamental right to property, and/or Article 20 of the Agreement on the Trade-related Aspects of Intellectual Property Rights). Japan Tobacco made a specific submission under this banner to protect the use of its 'Mild Seven' trade-mark for cigarettes.

The European Court of Justice declared the Directive valid in 2002.<sup>101</sup> However, the Court did rule that the ban on the use of

for second reading on the common position adopted by the Council with a view to adopting a directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products', COM(1999) 594 – C5–0431/2000 – 1999/0244(COD).  
R. Watson, 'MEPS back tougher health warnings on cigarette packets', *British Medical Journal* 322 (2001), 7.

<sup>100</sup> Case T-311/00, *British American Tobacco (Investments) Ltd v. Commission* [2002] ECR II-2781.

<sup>101</sup> Case C-491/01, *R v. Secretary of State for Health, ex parte British American Tobacco and Imperial Tobacco Ltd* [2002] ECR I-11453.

descriptors such as ‘lights’ and ‘mild’ should not apply to products manufactured for export outside of the EU.

A further legal challenge came in 2003, when seven tobacco companies, including BAT, Philip Morris, JTI and Imperial, filed separate challenges against the Dutch Government’s ingredient disclosure regulations (a transposition into national law of the Tobacco Products’ Directive), whereby tobacco companies were required to submit for publication ingredients and their quantity by brand. The industry claimed the by-brand information requested constituted trade secrets that competitors and counterfeiters would profit from if disclosed. In its judgement in 2005, the District Court of The Hague acknowledged this claim but ruled that trade secrets did not themselves enjoy absolute protection, and so the challenges were rejected.<sup>102</sup> Imperial Tobacco and others lodged an appeal in March 2006, which has yet to reach the Dutch courts.

The final challenge concerned the Directive’s ban on sales of certain types of oral tobacco – namely, snuff – first introduced in the 1992 Directive in all EU countries other than Sweden, and maintained in the 2001 Tobacco Products Directive. Challenges, brought by Match, a Swedish manufacturer of snuff, along with a German wholesaler, were rejected by the European Court of Justice in 2004.<sup>103</sup> Tobacco industry pressure for the ban to be lifted has continued. However, a subsequent review of the health effects of smokeless tobacco products by the Scientific Committee on Emerging and Newly Identified Health Risks, which recognized both the addictive nature and the health risks of smokeless tobacco, makes it unlikely the ban will be lifted in the near future.<sup>104</sup> This is, however, an area that is likely to be revisited for a variety of reasons. The industry’s interest in smokeless tobacco appears to be heightened by the spread of smoke-free legislation in Europe, which is encouraging people

<sup>102</sup> Case Nos. 207634, 207638, 207762 and 207765, *British American Tobacco v. Netherlands*, District Court of the Hague, 21 December 2005, <http://nl.vlex.com/vid/39426261>.

<sup>103</sup> Case C-210/03, *Swedish Match AB* [2004] ECR I-11893; Case C-434/02, *André v. Landrat des Kreises Herford* [2004] ECR I- 11825.

<sup>104</sup> Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), ‘Health Effects of Smokeless Tobacco Products’, Health and Consumer Protection Directorate-General, SCENIHR, February 2008, [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihr/docs/scenihr\\_o\\_013.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_013.pdf).

to quit smoking, accelerating the decline in cigarette sales. They anticipate that if smokers were able to use smokeless tobacco in environments where they are unable to smoke, it would help maintain their nicotine addiction and thus reduce the likelihood of their quitting as a result of smoke-free legislation.<sup>105</sup> But public health experts have also suggested that smokeless tobacco, which has a significantly lower health risk profile than smoked tobacco, could play a key role in tobacco control strategies by acting as a lower risk source of nicotine for addicted smokers unable to quit using conventional means.<sup>106</sup>

### C. Environmental tobacco smoke

As early as 1986, authoritative bodies in Europe<sup>107</sup> concluded that involuntary smoking was a cause of disease, including lung cancer. There is now incontrovertible evidence that exposure to other peoples' smoke is a cause of cancer, heart disease and other conditions.<sup>108</sup> It is also clear from industry documents – in particular, those concerning a secret testing plant in Germany operated by Philip Morris – that the industry has long been aware of the risks, yet has assiduously sought to confuse public

<sup>105</sup> M. McKee and A. Gilmore, 'Smokeless tobacco: seeing the whole picture', *International Journal of Epidemiology* 36 (2007), 805–8.

<sup>106</sup> Tobacco Advisory Group of the Royal College of Physicians, *Harm reduction in nicotine addiction: helping people who can't quit* (London: Royal College of Physicians, 2007).

<sup>107</sup> International Agency for Research on Cancer (IARC), *Monographs on the evaluation of the carcinogenic risk of chemicals to humans: tobacco smoking* (Lyon: World Health Organization, 1986); Scientific Committee on Tobacco and Health, *Report of the Scientific Committee on Tobacco and Health* (London: Stationery Office, 1998).

<sup>108</sup> K. Hackshaw, M. R. Law and N. J. Wald, 'The accumulated evidence on lung cancer and environmental tobacco smoke', *British Medical Journal* 315 (1997), 980–8; M. R. Law, J. K. Morris and N. J. Wald, 'Environmental tobacco smoke exposure and ischaemic heart disease: an evaluation of the evidence', *British Medical Journal* 315 (1997), 973–80; P. Boffetta *et al.*, 'Multicenter case-control study of exposure to environmental tobacco smoke and lung cancer in Europe', *Journal of National Cancer Institute* 90 (1998), 1440–50; Scientific Committee on Tobacco and Health, *Report of the Scientific Committee, ibid.*; National Cancer Institute, *Health effects of exposure to environmental tobacco smoke: the report of the California Environmental Protection Agency* (Bethesda: US Department of Health and Human Services, Public Health Service, National Institutes of Health, National Cancer Institute, 1999).

understanding and deter policy action in this area.<sup>109</sup> In the mid-1990s, for example, the industry undertook a major media campaign suggesting, misleadingly, that the risk of lung cancer from passive smoking was similar to that from everyday activities such as eating biscuits or drinking milk.<sup>110</sup> In parallel, it established a front organization, the 'European Working Group on Environmental Tobacco Smoke and Lung Cancer', which sought to discredit the evidence of risk by focusing, often misleadingly, on methodological issues.<sup>111</sup> Other challenges to the evidence were written by scientists who, as later revealed, were funded by the tobacco industry. A particularly notorious example was the industry's attempt to undermine a major study by the International Agency for Research on Cancer (IARC). The industry waged a three-pronged attack, spending more than twice that spent by IARC on the original study.<sup>112</sup> First, it commissioned research, directed by firms of lawyers, that would either contradict the findings or confuse the picture.<sup>113</sup> Second, it selectively leaked the IARC study, allowing the industry to present its own interpretation when the study was still undergoing peer review, so as to prevent the authors from responding. When the report was finally published, it was 'old news'. Third, the industry engaged in extensive political lobbying to counteract the report's findings, even managing to get the Commission to sponsor a seminar organized by an industry consultant that attacked the basis of the report.<sup>114</sup>

In its efforts to prevent legislation on smoke-free environments, the industry's key messages have been the promotion of cooperation and

<sup>109</sup> P. A. Diethelm, J. C. Rielle and M. McKee, 'The whole truth and nothing but the truth? The research that Philip Morris did not want you to see', *Lancet* 366 (2005), 86–92.

<sup>110</sup> G. Davey Smith and A. N. Phillips, 'Passive smoking and health: should we believe Philip Morris's "experts"?', *British Medical Journal* 313 (1996), 929–33; C. Colin and H. Maisonneuve, 'Misleading information on environmental tobacco smoke in the French lay press', *International Journal of Epidemiology* 26 (1997), 240–1.

<sup>111</sup> Davey Smith and Phillips, 'Passive smoking', *ibid.*

<sup>112</sup> E. K. Ong and S. A. Glantz, 'Tobacco industry efforts subverting International Agency for Research on Cancer's second-hand smoke study', *Lancet* 355 (2000), 1253–9.

<sup>113</sup> D. E. Barnes and L. A. Bero, 'Industry-funded research and conflict of interest: an analysis of research sponsored by the tobacco industry through the Center for Indoor Air Research', *Journal of Health Politics, Policy and Law* 21 (1996), 515–42.

<sup>114</sup> Ong and Glantz, 'Tobacco industry efforts', above n.112.

tolerance between smokers and non-smokers (to help maintain the social acceptability of smoking), and the use of ventilation as an alternative means of reducing exposure to environmental tobacco smoke, even though this is known to be ineffective.<sup>115</sup> The industry, largely through its front organizations, has consistently represented freedom to smoke as something accepted by most people, even non-smokers. Yet, even in 1995, a survey of EU citizens found that approximately 80% favoured legislation to prohibit smoking in places open to the public, including public transport. A similar percentage supported work-place bans.<sup>116</sup> The industry's own data showed not only that 79% supported bans and 60% supported legislative restrictions, but that 86% believed environmental tobacco smoke to be harmful.<sup>117</sup>

Although the EU lacks the legal competence to legislate on smoking in public places (other than those that are also work-places), it does have the authority, under the rubric of health and safety at work, to legislate against smoking in the work-place. Thus Directive 89/654/EEC<sup>118</sup> required that 'in rest rooms and rest areas appropriate measures must be introduced for the protection of non-smokers against the discomfort caused by tobacco smoke'. It has also combined such binding measures with non-binding resolutions and recommendations. In 1989, the Council of Ministers issued a resolution that invited Member States to implement policies on smoking in public places, using legislation or other methods.<sup>119</sup> In 1992 and 1996,<sup>120</sup> the Commission reviewed the measures taken by Member States, linking measures by a number of

<sup>115</sup> P. Pilkington and A. B. Gilmore, 'The Living Tomorrow Project: how Philip Morris has used a Belgian tourist attraction to promote ventilation approaches to the control of second hand smoke', *Tobacco Control* 13 (2004), 375–8.

<sup>116</sup> European Commission, 'European survey: Strong support for anti-smoking measures', *Prevention* 2 (1997), 14–5.

<sup>117</sup> Morris, 'Smoking restrictions', above n.80.

<sup>118</sup> Council Directive 89/654/EEC concerning the minimum safety and health requirements for the work-place (first individual directive within the meaning of Article 16(1) of Directive 89/391/EEC), OJ 1989 No. L393/1.

<sup>119</sup> Council and Ministers for Health of the Member States Resolution on banning smoking in places open to the public, OJ 1989 No. C189/1.

<sup>120</sup> European Commission, 'Report from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee on the response to the Resolution of the Council and the Ministers for Health and the Member States meeting on banning smoking in places open to the public', COM (96) 573 final, 14 November 1996.

Member States to the resolution, but conceding that it was not possible to attribute changes to it directly. In 2002, the Council once again reiterated the need for Member States to take action on smoke-free workplaces, public places and transport through the 2002 Recommendation described above.<sup>121</sup> In 2007, the Commission issued a Green Paper entitled 'Towards a Europe free of tobacco smoke', which aimed to explore the best way to tackle involuntary smoke exposure in the EU.<sup>122</sup> Responses indicated that the vast majority supported the Commission's view that only a comprehensive ban on smoking in enclosed places offers adequate protection and that strengthened action at both Member State and EU level is required to achieve this, prompting the Commission to launch a follow-up initiative by the end of 2008.

Thus, despite the limitations on EU competence in this area, smoke-free policies have developed considerably in recent years, as, one after another, Member States are acting on their own initiative to implement smoke-free public places.<sup>123</sup> Even in Germany, which has traditionally opposed any action against smoking, there are signs of change,<sup>124</sup> although in others, such as Austria, where the formerly state-owned monopoly, Austria Tabac, remains highly influential, little has happened. Inevitably, the industry has worked hard to oppose such policies, arguing in particular that they will have an adverse impact on the hospitality industry, a claim that is without foundation. In all cases where bans have been implemented, they have been successful and have been associated with an increase in support for them, including among existing smokers. While it is not possible to ascribe a causative effect to EU soft law measures, it is possible that the accretion of EU resolutions, recommendations, green papers, consultations and the like do have some impact on changes at national level. They may also eventually build towards EU legislation, in situations where legal competence exists and the necessary political allegiances can be formed within the EU's legislative processes.

<sup>121</sup> Council Recommendation on the prevention of smoking and on initiatives to improve tobacco control, OJ 2003 No. L22/31.

<sup>122</sup> European Commission, 'Towards a Europe free of tobacco smoke: policy options at EU level', Green Paper, COM (2007) 27 final, 30 January 2007.

<sup>123</sup> S. Chapman, 'The future of smoke-free legislation', *British Medical Journal* 335 (2007), 521–2.

<sup>124</sup> T. Gruning and A. Gilmore, 'Germany: tobacco industry still dictates policy', *Tobacco Control* 16 (2007), 2.

#### D. Price and taxation

In 1992, the EU adopted three directives, effective from 1 January 1993, designed to harmonize tobacco taxation across its Member States.<sup>125</sup> These directives relate to the three principal forms of taxation on cigarettes: value-added tax (VAT), fixed specific excise duty (imposed as a fixed amount per 1000 pieces or grams) and variable or *ad valorem* excise duty (proportional to the final retail price). The *ad valorem* tax leads to price differentials between cheaper and more expensive brands that increase as the percentage level of the tax itself increases – the so-called ‘multiplier effect’. A system based largely on *ad valorem* tax therefore allows more affordable cigarettes to exist on the market, but has the advantage of automatically taking account of inflation. In contrast, since specific duties (by adding a fixed price to every cigarette regardless of its baseline price) do not have this multiplier effect, they reduce price differentials and lead very cheap brands to be withdrawn from the market. These duties have to be increased regularly to allow for inflation.

The three directives introduced in October 1992 were a compromise between those in favour of *ad valorem* taxation (generally, the southern European tobacco-growing Member States seeking to keep the cheaper cigarettes containing home-grown tobacco on the market) and those in favour of specific taxation (generally, the northern European tobacco-manufacturing Member States). The directives stipulate that each Member State should apply an *overall* excise duty (specific and *ad valorem* combined) of at least 57% of the final retail selling price of the price category most in demand. In addition, the minimum specified VAT rate was set at 13.04%, meaning that the minimum overall level of taxation on cigarettes was required to be 70%. Countries were free to set the balance between *ad valorem* and specific taxation – on the condition that the latter falls in the range of 5–55%, as previously agreed in the *acquis communautaire*. As a result, while leading

<sup>125</sup> Council Directive 92/80/EEC on the approximation of taxes on manufactured tobacco other than cigarettes, OJ 1992 No. L316/10; Council Directive 92/78/EEC amending Directives 72/464/EEC and 79/32/EEC on taxes other than turnover taxes which are levied on the consumption of manufactured tobacco, OJ 1992 No. L316/1; Council Directive 92/41/EEC amending Directive 89/622/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products, OJ 1992 No. L158/30.

to price increases in a number of countries, these directives did not eliminate large price differentials. By the same token, very cheap cigarettes continued to be produced, distributed and sold.

In 1995, a Commission review raised two major concerns: that the 57% rule had widened price differences between Member States, which was not in the interest of the internal market, and that an increase in manufacturers' prices would lead to an increase in retail prices, which might result in the overall excise falling below the 57% minimum. It later became apparent that these concerns had been fuelled by the tobacco industry's lobbying effort, which had succeeded in confusing the Commission.<sup>126</sup> Unable to agree on a way forward, the Commission held an excise conference in July 1995. One health organization and forty-two industry representatives attended. The industry journal *Tobacco International* described the meeting as a 'triumph for the national industries'. It noted that, while Member States generally intervene or respond only after the Commission has formulated a proposal, the industry intervened earlier in this case: 'while the Commission was in the process of formulating its proposals the industry could, and did, intervene – this time successfully'.<sup>127</sup> As a result of the lobbying – and despite the reduction in price differences from 623% in January 1992 to 372% in September 1996<sup>128</sup> – the Commission revised the Taxation Directive in 1999. This change gave Member States greater flexibility in setting taxes but did little to reduce the price differentials within Europe.<sup>129</sup>

The Commission expressed a desire to further harmonize minimum taxation levels in order to respond to public health concerns,<sup>130</sup>

<sup>126</sup> Joossens, 'Comments on Commission report', above n.73.

<sup>127</sup> R. Garran, 'Setback for RYO: EU tobacco tax harmonisation', *Tobacco International* (1995), 43–5.

<sup>128</sup> In April 2001, the price differential was just under 400%, the cost of a pack of 20 varying from a maximum of £4.33 in the United Kingdom to a minimum of £1.10 in Spain. See [www.the-tma.org.uk/statistics/eu\\_facts\\_figures\\_98.htm](http://www.the-tma.org.uk/statistics/eu_facts_figures_98.htm).

<sup>129</sup> Council Directive 1999/81/EC amending Directive 92/79/EEC on the approximation of taxes on cigarettes, Directive 92/80/EEC on the approximation of taxes on manufactured tobacco other than cigarettes and Directive 95/59/EC on taxes other than turnover taxes which affect the consumption of manufactured tobacco, OJ 1999 No. L211/47.

<sup>130</sup> European Commission, 'Progress achieved in relation to public health protection from the harmful effects of tobacco consumption', COM (99) 407 final, 8 September 1999.

and issued a new directive designed to reduce price differentials and drive very cheap brands from the market. Adopted in February 2002, Directive 2002/10/EC<sup>131</sup> supplements the 57% rule with the requirement that the minimum total excise rate must be at least €60 per 1000 cigarettes (and €64 per 1000 by July 2006).<sup>132</sup> Alternatively, countries can be exempted from the 57% requirement if they have a minimum total excise duty of €95 per 1000 cigarettes (and €101 per 1000 by July 2006). A number of northern European countries currently fall under that provision.<sup>133</sup>

Unfortunately, however, the new Member States, despite moving towards tax harmonization since the 1990s, were allowed inordinately long delays before having to implement the full EU cigarette excise rates. This has resulted not only in a fall in real prices in most new Member States, but also led to wider price differentials within the EU.<sup>134</sup> Moreover, in 2009 the Court heard a claim brought by the Commission against three Western Member States, to the effect that national rules setting minimum prices for tobacco products (to prevent using tobacco as a loss leader), breached the terms of the directive.<sup>135</sup>

### *E. Industry lobbies, tobacco regulation and EU law*

It is apparent that the tobacco industry has played a key role in subverting European tobacco-control policy, acting at all levels of European policy-making. Some of its activities have involved overt lobbying, but it has also engaged in extremely influential covert methods. It created 'grass roots' smoking-rights groups such as FOREST in the United Kingdom or Hen-Ry ('courteous smokers') in Scandinavia.<sup>136</sup> It also used a variety

<sup>131</sup> Council Directive 2002/10/EC of 12 February 2002 amending Directives 92/79/EEC, 92/80/EEC and 95/59/EC as regards the structure and rates of excise duty applied on manufactured tobacco, OJ 1992 No. L46/26.

<sup>132</sup> ASPECT Consortium, *Tobacco or health*, above n.82; A. Gilmore *et al.*, 'Free trade versus the protection of health: the examples of alcohol and tobacco', in M. McKee, L. MacLehose and E. Nolte (eds.), *Health policy and European Union enlargement* (Maidenhead: Open University Press, 2004), pp. 22–42.

<sup>133</sup> Gilmore *et al.*, 'Free trade', in *ibid.*

<sup>134</sup> ASPECT Consortium, *Tobacco or health*, above n.82.

<sup>135</sup> Cases C-197–8 and 221/08 *Commission v. France, Austria and Ireland*, Opinion of the AG (Kokott) 22 October 2009.

<sup>136</sup> S. Carlson, 'World Congress of Smokers Rights Groups (SRG's)', Philip Morris, Bates No. 2500041706–9 (1982); P. Morris,

of front groups, such as ostensible hospitality associations, to oppose smoke-free environments.<sup>137</sup> Other organizations were used to present industry arguments and distort scientific evidence. One tactic that has had considerable success is the industry's support for libertarian arguments, stressing freedom to smoke, and engaging human rights or civil liberties rhetoric and law. This has been used with particular effect to oppose bans on smoking in public places, with calls to non-smokers to show 'tolerance', and labeling those opposed to smoking as 'health fascists' or 'nico-Nazis',<sup>138</sup> with the latter exploiting a distorted version of the situation during the Third Reich.<sup>139</sup> It is now apparent that many libertarian organizations and commentators, such as the philosopher Roger Scruton, whose attacks on WHO's Framework Convention are widely cited,<sup>140</sup> were funded by tobacco companies.

The unsteady progress of legislation to tackle tobacco within the EU is of interest not just because of its implications for public health. National politicians have often criticized what they portray as the democratic deficit in the EU, arguing that Members of the European Parliament are remote from their constituents, and that the EU legislative procedures, involving the Commission, Council and the European Parliament, lack legitimacy.<sup>141</sup> However, in the

'Communication – smokers' organizations', *Infotopics: summaries of public information* 6 (1987), 39; T. V. Dineson, 'Interim report on the Hen-Ry promotion campaign', Philip Morris, Bates No. 2023270359–60 (1989); D. S. Harris, 'Memo on public relations effort being conducted by Hen-Ry', Philip Morris, Bates No. 2023270361–2 (1989).

<sup>137</sup> J. V. Dearlove, S. A. Bialous and S. A. Glantz, 'Tobacco industry manipulation of the hospitality industry to maintain smoking in public places', *Tobacco Control* 11 (2002), 94–104.

<sup>138</sup> J. E. Cohen *et al.*, 'Political ideology and tobacco control', *Tobacco Control* 9 (2000), 263–7.

<sup>139</sup> E. Bachinger and M. McKee, 'Tobacco policies in Austria during the Third Reich', *International Journal of Tuberculosis and Lung Disease* 11 (2007), 1033–7.

<sup>140</sup> A. Ferriman, 'Vilified for attacking tobacco', *British Medical Journal* 320 (2000), 1482.

<sup>141</sup> See, for example, J. Weiler, *The constitution of Europe* (Cambridge: Cambridge University Press, 1999); P. Craig and C. Harlow (eds.), *Lawmaking in the European Union* (Deventer: Kluwer, 1998); P. Craig, 'The nature of the Community: integration, democracy and legitimacy', in P. Craig and G. de Búrca (eds.), *The evolution of EU law* (Oxford: Oxford University Press, 1999). For an excellent summary, see P. Craig and G. de Búrca, *EU law* (Oxford: Oxford University Press, 2008), pp. 133–42.

debate about tobacco, it is the Parliament, debating in public, that has consistently reflected the views of European citizens, expressed through opinion polls. In contrast, it is the Council of Ministers, meeting in secret, that has often sided with the tobacco industry and against the interests of citizens. Further efforts to ensure transparency and wider public involvement in the EU's public health law and policy-making processes might therefore benefit the quest for effective tobacco regulation.

Our account of the development of EU tobacco law also exposes an aspect of the legislative process that is often hidden – the sometimes powerful role of lobbyists. In some cases, the lobbying is targeted directly at the EU institutions. In others, it is somewhat more insidious, taking place within Member States and hidden far from view. The opening of tobacco industry archives under court orders in the United States has shed some light on this process. An example is the exposure of long-standing industry funding for a number of eminent and highly influential epidemiologists and public health specialists in Germany, a factor that cannot be ignored when seeking to understand the persistent opposition by successive German Governments to effective tobacco control.<sup>142</sup> It is, however, extremely unlikely that lobbying and related tactics such as have been exposed in relation to tobacco are not taking place in other areas of importance for public health.

## 5. Looking forward

The policies of the EU impact on health in many different ways, from the environment in which its citizens live, the jobs that they do and the food that they eat. Only a fraction of these lie within the remit of what might be described as a public health policy, and, in some cases, decisions are made on other grounds that impact adversely on health. This is despite the provisions of Article 152 EC that '[a] high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities'.

<sup>142</sup> T. Gruning, A. B. Gilmore and M. McKee, 'Tobacco industry influence on science and scientists in Germany', *American Journal of Public Health* 96 (2006), 20–32.

Given the limited resources that have been available to DG SANCO, which has formal responsibility for health, it can be understood, but not justified, why, so far, it has failed to assess the health impacts of policies in other areas. However, in the medium term, this situation does not seem tenable, and its failure may even be open to legal challenge.<sup>143</sup> Such assessments could have a major influence on EU policy, although they would also be extremely controversial.

Turning to the areas more usually considered to fall within the remit of public health, the case studies explored in this chapter show that a wide spectrum of different roles for EU law and policy are at play. The EU institutions have used a range of different regulatory techniques, sometimes blending a variety of different techniques within a particular policy field. The spectrum of roles for EU law ranges from regulation through the provisions of internal market law, through to soft law and the use of information to exercise control and effect change.

At the more 'regulatory' end of the spectrum, restrictions on the free movement of persons and goods in pursuit of protection of public health are permitted within internal market law, although they are subject to scrutiny by reference to the proportionality principle. There is EU-level regulation of the contents and labelling of products that involve or may involve a public health risk (the example we have discussed here is tobacco products; other examples include toys,<sup>144</sup> products made from genetically modified organisms<sup>145</sup> and food for which health claims are made).<sup>146</sup> This is not problematic from the point of view of EU law, since these matters are regulated in order to ensure that the goods can be lawfully marketed across the EU. However, as this chapter has shown, as the setting in which legislation is enacted has moved to the EU, so the industry lobby has followed.

<sup>143</sup> For instance, under Article 232 EC, action for 'failure to act', perhaps brought by the European Parliament.

<sup>144</sup> Council Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys, OJ 1988 No. L187/1.

<sup>145</sup> European Parliament and Council Directive 2008/27/EC amending Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, as regards the implementing powers conferred on the Commission, OJ 2008 No. L81/45.

<sup>146</sup> European Parliament and Council Regulation 1924/2006/EC of the European Parliament and of the Council on nutrition and health claims made on foods (corrected version), OJ 2006 No. L44/1.

More controversially, the regulation of *advertisements* for products involving or potentially involving public health risks has also been taken up at the EU level. Part of the reason for the controversy is the lack of 'fit' between this regulation and its legal basis in EU law, that of the internal market. As we have seen, the tobacco advertising litigation, in particular at the suit of Germany and various tobacco industry litigants, has to some extent impeded the EU institutions from effecting change in public health policy. The EU's regulation of taxation of tobacco products shows a similar lack of 'fit' between EU legal bases and the public health aims behind taxation of tobacco products, which essentially aim to discourage people from taking up smoking and to encourage smokers to quit. The Court's rulings in both *Tobacco Advertising* cases make it clear that the EU may not lawfully use internal market law simply to achieve public health goals.

At the other end of the spectrum, there are areas, such as that of environmental tobacco smoke, where policy changes in the Member States cannot be attributed directly to any formal Europeanization processes. However, it is widely believed that much greater interaction between members of the public health community, supported by the EU, has played a role in the diffusion of such ideas. In this way, convergence of national policies has taken place without any direct (or possibly even indirect) involvement of the EU institutions.

This chapter began by identifying a series of tensions at the heart of European public health policy. Until these can be resolved, if this is possible, the EU institutions, with their limited resources, will find it very difficult to develop a comprehensive public health policy. Instead, they must select particular legal and policy niches where they have the legislative competence, the political support and the relevant evidence to act.

Given the constraints that they face, one area that is open to them is what Terence Daintith has called 'government by dominium'<sup>147</sup> – that is, using the wealth of governing institutions to achieve policy aims. Of course, the EU's available funds are relatively small, but they have been used judiciously, in carefully selected policy areas. As the EU's activities in communicable disease control illustrate, very small scale beginnings, with only short term funding, have led, through their own

<sup>147</sup> T. Daintith, 'The techniques of government', in D. Oliver and J. L. Jowell (eds.), *The changing constitution* (Oxford: Clarendon Press, 1994), p. 470.

successes and also external pressures, to large scale, more integrated sets of policy-making tools and institutions, supported by a long term financial framework. The EU has exercised influence through information collection, dissemination, development of best practice and networking. The roles of formal, hard law in this respect are minimal (e.g., extending only to obligations to report information in particular formats). Yet the overall influence on policy may be more significant than the formal legal position implies.

Fundamentally, however, those who are developing public health policy at a European level must work within the framework established by EU law. EU internal market law, although based on free trade, which can pose challenges for public health, does allow for restrictions on free movement necessitated by public health protection. Several components of internal market legislation, especially those that address consumer protection, promote public health. Examples include measures in the area of food law. However, the need to frame such legislation within the parameters of Article 95 EC leaves scope for legal challenges if the legislation is too restrictive of free movement, even if this would best protect or promote public health interests. We have seen this in the context of tobacco regulation: similar processes could be imagined were the EU to take forward legislation on the sale and marketing of alcohol, an action that would be justified on the basis of the consequences for health of existing EU internal market policies.<sup>148</sup>

While Article 152 EC explicitly prohibits the adoption of binding EU-level laws designed to protect and improve human health and that set harmonized EU standards, the legal basis of Article 152 EC has allowed the EU to develop the Public Health Programmes. There is also specific EU legislation on some public health areas where the EU and its Member States cooperate within existing international public health structures.

## 6. Conclusion

Faced with the responsibility of developing public health policy, in the context of insufficient resources and competences to develop the full

<sup>148</sup> M. McKee, 'A European alcohol strategy: will the opportunity be missed?', *British Medical Journal* 333 (2006), 871–2.

range of policies and practices that make up national public health and insufficient expertise and experience to become an international public health actor, the EU has adopted a piecemeal approach, based on the 'art of the possible'. What we have examined in this chapter are some of the pockets of public health activity undertaken by the EU. Any attempt to assess the EU's *overall* approach to public health as if it were responsible for either a state-like or a supranational public health policy would conclude that the EU has not been successful in developing an all-encompassing approach to promoting and embedding public health matters within all its policies and practices. Nor can it be said that the EU has made a demonstrable contribution to the improvement of public health, generally speaking, across all of its territory. Equally, the EU cannot possibly develop equivalent competence in international public health to that of specialist international organizations dealing with public health, such as WHO. Where the EU has been successful, as our case studies show, is in directing its meagre public health resources into 'niche' areas of activity, where there are obvious contributions to be made through acting at the EU rather than the national or international levels. EU public health activities have been more successful where the EU institutions are relatively open to contributions from all stakeholders, rather than subject to lobbying from only certain stakeholders. We therefore suggest that a valuable future direction for the EU's public health policy would be to continue to focus on specific areas of activity and to develop sharper and more precise priorities, through transparent processes, informed by evidence on the burden of disease and the effectiveness of policies.