

# European (Legal) Studies on-line papers

Queen's University Belfast - School of Law – Centre of European and Transnational Legal Studies

<http://go.qub.ac.uk/law-cetls>



*MARK L. FLEAR*

## **Reframing Public Health Governance: From Risk to Citizenship and Participation**

**Volume 4, Issue 3, 2015**

These on-line papers are part of the programme provided under the Jean Monnet ad Personam Chair held by Professor Dagmar Schiek, which was part-funded by the EU Commission from September 2011 to August 2014 (University of Leeds)

This paper is the pre-print version of a book chapter, and will be published in: D. Kochenov (ed) *EU Citizenship and Federalism: The Role of Rights*, Cambridge University Press, in preparation – 2015

# Reframing Public Health Governance: From Risk to Citizenship and Participation

---

Mark L. Flear\*

## I. Introduction

Risk is the dominant frame for the European Union's (EU's) growing albeit often overlooked public health governance.<sup>1</sup> The starting point for this chapter is the distortion of public health priorities by and within this frame. I argue that existing efforts to identify, underline and tackle the distortions can be strengthened by reframing governance as a matter of citizenship so as to develop citizen participation in decision making. The chapter therefore seeks to add to discussion on EU citizenship within this collection and beyond, which focuses on judicial discourse on *inter alia* rights, responsibilities, needs and entitlements.<sup>2</sup> The chapter not only raises awareness of but also offers a novel proposal for mobilising the discursive potential of key elements of citizenship for participation.

In the next (second) section, I explain how EU governance and its frame are founded upon Article 168 Treaty on the Functioning of the EU (TFEU),<sup>3</sup> elaborated in policy statements, and related to the production and legitimation of the broader project of European integration. The frame depoliticises, renders as natural and obscures the true scope of EU governance and its distortion of public health priorities. These latter include the skewing of attention and resources towards addressing consequences through efforts to combat rarer communicable diseases, instead of the root causes that are vital to tackling far more common and deadly major and chronic diseases. This distortion of priorities is similar to the broader global trend of emphasising health security above other important health concerns. Most notable in that regard are the World Health Organisation's (WHO) International Health Regulations (IHR) (applicable to the EU)<sup>4</sup> and the Global Health Security Initiative (with which the EU cooperates),<sup>5</sup> both of which attempt to strengthen health preparedness and response globally in order to address all hazards.

Citizen participation in decision making is part of attempts to identify and correct distortions of regulatory priorities and enhance trust in risk-based governance. However, participation tends to be an

---

\* Queen's University Belfast. This paper profited from valuable suggestions by Dimitry Kochenov and the anonymous peer reviewers, which are gratefully acknowledged. The usual disclaimer applies.

1 See further M. L. Flear, *Governing Public Health: EU Law, Regulation and Biopolitics* (Oxford: Hart Publishing, 2015).

2 In particular: A. Cornwall and V. Schatten Coelho (eds.), *Spaces For Change?: The Politics of Citizen Participation in New Democratic Arenas* (London: Zed Books, 2007); H.-U. Jessurun d'Oliveira, 'European Citizenship: Its Meanings, its Potential', in R. Dehousse (ed.), *Europe After Maastricht: An Ever Closer Union?* (Munich: Law Books in Europe, 1994); D. Kostakopoulou, *The Future Governance of Citizenship* (Cambridge: Cambridge University Press, 2008); J. Shaw, 'The Many Past and Futures of Citizenship in the European Union' (1997) 22 *European Law Review* 554; A. Wiener, *'European' Citizenship Practice: Building Institutions of a Non-State* (Oxford: Oxford University Press, 1998).

3 Consolidated version of the Treaty on the Functioning of the European Union (TFEU), OJ 2012 No. C326/47.

4 International Health Regulations (WHA58/2005/REC/1, 23 May 2005) (IHR). These require WHO Member States to notify the WHO of any potential international public health emergency and are applicable to the EU under Article 57(1) IHR, which states the IHR and EU Treaties 'should be interpreted so as to be compatible'.

5 See 'Global Health Security Initiative', <http://www.ghsi.ca/english/index.asp>.

underdeveloped and underpowered governance tool.<sup>6</sup> Later in the second section I point out that a large part of the explanation for this is the way in which decision making in risk-based EU governance is supported by and necessitates the gathering and production of scientific and technical knowledge. The latter in turn valorises those in possession of the expertise to interpret that knowledge for the determination of public health risks. In short, the framing of governance by risk operates ‘top-down’ with complementary discourses and techniques to obscure the stakes for citizen participation in decision making while also limiting its regulatory role through the very procedures that seek to facilitate it.

I begin the third section by noting how the focus on procedures and a limited view on the regulatory potential of participation is also found in legal and regulatory studies scholarship. After which by reference to science and technology studies (STS), sociology and anthropology I underline the value of and potential for ‘bottom-up’ engagement and participation. A related key contribution of the chapter, therefore, is towards the growing body of literature which seeks to frustrate the law/science disciplinary demarcations that limit the engagement of much legal and regulatory studies scholarship in teasing out the normative and democratic implications of the scientific and technical.<sup>7</sup> By drawing on these cognate disciplines I point out how the distortion of public health priorities by risk-based governance, and the importance of that governance for the legitimation of the EU and the wider project of European integration, creates possibilities for using components of citizenship as part of ‘bottom-up’ efforts to develop citizen participation in decision making.

With this in mind I turn to outline my proposal for augmenting citizen participation as a tool of governance. I point to citizenship’s potential to reframe public health as a field for citizen participation in legal and regulatory decision making, public discussion and democratic contestation. The discussion is based on an understanding of (EU) citizenship as a technology of governance or as an assemblage of components. These components go beyond formal rights recognised in the EU’s constitutional legal order – such as Article 35 EU Charter of Fundamental Rights (CFR)<sup>8</sup> on the right to healthcare, the European Convention of Human Rights<sup>9</sup> and wider human rights provisions – to encompass bioethics, other discourses, techniques, processes and practices of governance, which together shape and provide the conditions of possibility for and mediate relations between those subject to and governed by formally accountable power (such as the EU).<sup>10</sup> In this understanding the ‘citizens’ mentioned in this chapter comprise more than those with rights under the EU Treaties<sup>11</sup> to include those that are

---

6 For discussion see: D. Held, ‘Between State and Civil Society: Citizenship’, in G. Andrews (ed.), *Citizenship* (London: Lawrence and Wishart, 1991). Citizen and public participation tend to be used interchangeably in scholarship: M. L. Flear and M. D. Pickersgill, ‘Regulatory or Regulating Publics? The European Union’s Regulation of Emerging Health Technologies and Citizen Participation’ (2013) 21 *Medical Law Review* 39.

7 For instance: E. Cloatre and M. Pickersgill (eds.), *Knowledge, Technology and Law* (London: Routledge, 2014); A. Daemmrich, *Pharmacopolitics: Drug Regulation in the United States and Germany* (Chapel Hill, NC: University of North Carolina Press, 2006); S. Jasanoff (ed.), *Reframing Rights: Bioconstitutionalism in the Genetic Age* (Cambridge, MA: MIT Press, 2011).

8 Charter of Fundamental Rights of the European Union (CFR), OJ 2012 No. C326/391.

9 The CFR is given the ‘same legal value as the Treaties’ under Art. 6(1) TEU, respect for human rights is mentioned in Art. 2 TEU, and Art. 6(3) TEU makes ‘fundamental freedoms’ as guaranteed by the ECHR (with accession provided for under Art. 6(2) TEU) and ‘constitutional traditions common to the Member States’, general principles of EU law.

10 J. Newman (ed.), *Remaking Governance: Peoples, Politics and the Public Sphere* (Bristol: Policy Press, 2005); A. Ong, *Neoliberalism as Exception: Mutations in Citizenship and Sovereignty* (Durham, NC: Duke University Press, 2006).

11 In particular Art. 20(1) TFEU states ‘[c]itizenship of the Union is hereby established. Every person holding the nationality of a Member State shall be a citizen of the Union. Citizenship of the Union shall be additional to and not

subject to and enfolded within EU governance and comprise ‘the governed’, but who can reflexively engage with and genuinely share in power in order to shape and steer governance.<sup>12</sup>

To be clear, I am not proposing the wholesale replacement of risk by citizenship as the most appropriate value for the determination and regulation of public health risks. Rather, in this chapter I point to the potential of human rights and bioethics – two important regulatory discourses and components of citizenship – to animate and power ‘bottom-up’ engagement by citizens and assist them in the identification and underlining of distortions in governance priorities. Once identified and articulated through human rights and bioethics, the distortions of governance priorities or ‘societal risks’ (i.e. threats or dangers to society) can be transformed into supplementary knowledge on ‘institutional risks’ (i.e. more than the legal risk of litigation: broader threats or dangers to standing and reputation).<sup>13</sup> Such knowledge of risks not only threatens to undermine perceptions of EU public health governance but also to disrupt the legitimation and perpetuation of the European integration project. It is the threat of de-legitimation which could impel the integration of citizen knowledge into decision making. The discursive strategy for citizen participation outlined in this chapter promises to reveal the full scope and implications of EU governance, enhance accountability through attempts to demand and contest the fulfilment of EU responsibilities, reshape and rebalance governance priorities, and improve regulatory interventions in public health.

## II. Framing EU Public Health Governance as a Matter of Risk

### A. Legal Competence, Governance and Responsibility

Risk is constructed as the dominant frame for the EU’s public health governance through limited legal competence which is elaborated in policy in order to delineate the boundaries of responsibility and accountability in the event of failure.<sup>14</sup> The discussion in this chapter concerns EU public health governance based upon Article 168 TFEU, rather than a broader consideration of the various areas of EU competence which together relate to public health. The internal market is probably the most important example of an area of EU competence that relates to public health and, as I shall note below, Article 168 plays an important role in facilitating its functioning.<sup>15</sup> Article 168(1) TFEU states a ‘*high level of human health protection shall be ensured*’ in the definition and implementation of *all Union policies and activities*’ (emphasis added). Article 168(1) is a more specific instance of Article 9 TFEU, which states ‘the Union shall take into account requirements linked to [...] *a high level of...protection of human health*’ (emphasis added) in the definition and implementation of its policies and activities. These provisions reflect Article 35 CFR on the right to healthcare, the final part of which states: ‘A

---

replace national citizenship’.

<sup>12</sup> Foundational to the understanding of citizenship informing the discussion in this chapter is Foucault’s notion that power is relational and dispersed throughout society, including its institutions and discourses, see: M. Foucault, *Power, Essential Works of Foucault 1954–1984*, Volume 3 (London: Penguin, 2002), especially ‘Governmentality’. See further the references in notes 83–86 below.

<sup>13</sup> For discussion see H. Rothstein, M. Huber and G. Gaskell, ‘A Theory of Risk Colonisation: The Spiralling Regulatory Logics of Societal and Institutional Risk’ (2006) 35 *Economy and Society* 91.

<sup>14</sup> For discussion of risk-based regulation and responsibility see J. Black, ‘The Emergence of Risk-Based Regulation and the New Public Risk Management in the United Kingdom’ (2005) *Public Law* 512.

<sup>15</sup> The establishment of the internal market is required by Art. 3(3) TEU, which is defined in Art. 26(2) TFEU as ‘an area without internal frontiers in which the *free movement* of goods, persons, services and capital is ensured [...]’. For discussion on this and Art. 168 TFEU see Flear, *Governing Public Health*, note 1 above, ch. 2.

*high level of human health protection* shall be ensured in the definition and implementation of *all the Union's policies and activities*' (emphasis added). According to the Explanatory Note for Article 35 this final sentence takes over Article 168(1). Consistent with Article 6(a) TFEU, EU action in health is only complementary to Member State policies, and it must be of 'added value' to comply with the principles of subsidiarity<sup>16</sup> and proportionality<sup>17</sup> under Article 5 Treaty on European Union (TEU).<sup>18</sup>

The limited nature of EU competence is even more apparent in Article 168(1)(2) TFEU, which provides that EU action:

*shall be directed towards improving public health...obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health (emphasis added).*

This provision makes clear that EU competence extends beyond efforts to address the social determinants of ill health and to promote prevention of the major public health problems,<sup>19</sup> to include specific mention of pandemics and other serious cross-border threats,<sup>20</sup> through the gathering and production of scientific and technical knowledge on those threats. However, the clear limits on EU competence are further underlined by the requirement that the EU must also respect Member State responsibilities over 'the *definition* of their health policy and for the *organisation and delivery* of health services and medical care' (emphasis added) in Article 168(7) TFEU. A fuller analysis would of course extend beyond the EU level to look at interactions between multiple levels of governance.<sup>21</sup> Such an analysis is not possible in this chapter length piece, which in any case seeks to shed light on the EU level as a key albeit often overlooked part of that wider discussion.<sup>22</sup>

Nevertheless, within the limits on EU action found in Article 168 TFEU there are certain priorities for regulatory attention. Specifically, Article 168(2) TFEU provides the legal basis for encouraging cooperation and the adoption of measures, including guidelines and indicators, the exchange of best practice, and mechanisms for periodic monitoring and evaluation. Although Article 168(5) TFEU precludes the adoption of harmonisation measures, it provides for the adoption of 'incentive measures designed to protect and improve human health and *in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health*' (emphasis added). In building on Article 168(1)(2) TFEU to give pandemics and other serious cross-border threats special attention, the latter provision paves the way for a focus on efforts to ensure preparedness and response. An important piece of legislation adopted under

---

16 Art. 5(3) TEU.

17 Art. 5(4) TEU.

<sup>18</sup> Consolidated version of the Treaty on European Union (TEU), OJ 2012 No. C326/13.

<sup>19</sup> For example cancer and HIV/AIDS, see Flear, *Governing Public Health*, note 1 above, chs. 3 and 4 respectively.

<sup>20</sup> See *ibid.*, ch. 5.

<sup>21</sup> The discussion focuses on the EU level, which is one level of the multi-level system of governance. See further: L. Hooghe and G. Marks, *Multilevel Governance and European Integration* (Oxford: Rowman & Littlefield, 2001).

<sup>22</sup> The literature on the 'democratic deficit' is vast and some of the most salient examples include: C. Harlow, *Accountability in the European Union* (Oxford: Oxford University Press, 2002); G. Majone, 'Europe's "Democratic Deficit": The Question for Standards' (1998) 4 *European Law Journal* 5; F. W. Scharpf, *Governing in Europe. Effective and Democratic?* (Oxford: Oxford University Press, 1999).

Article 168(5) is Decision 1082/2013/EU<sup>23</sup> on *serious cross-border threats to health*,<sup>24</sup> which is intended to strengthen surveillance and control, and reflects the IHR.<sup>25</sup> This skewing of priorities towards cross-border threats is supported by and helps to explain Article 168(3) TFEU, which provides that both the EU and its Member States ‘shall foster cooperation with *third countries* and the *competent international organisations* in the sphere of public health’ (emphasis added). Overall, Article 168 TFEU provides the scope for greater cooperation and coordination between Member State law and policy and thus more intrusive engagement in public health. The overriding concern is with the circulation of people and things *within* and *into* the internal market by regulating the dangers or threats that threaten to undermine its optimal functioning.

2007’s *Together for Health: A Strategic Approach for the EU 2008–2013*<sup>26</sup> builds on the formal legal basis to construct risk as the dominant frame of public health governance. The EU’s strategy purports to ‘give direction to Community activities in health’.<sup>27</sup> The rationale for EU action builds on Article 168 TFEU in stating that the:

*Member States have the main responsibility for health policy and provision of healthcare to European citizens. The EC’s [European Community’s and now the EU’s] role is not to mirror or duplicate their work. However, there are areas where Member States cannot act alone effectively and where cooperative action at Community level is indispensable. These include major health threats and issues with a cross-border or international impact, such as pandemics and bioterrorism, as well as those relating to free movement of goods, services and people.*<sup>28</sup>

EU competence is underscored as supporting and complementary to that of the Member States and focused on generating ‘added value’ through cooperation to tackle public health problems. Among the latter, pandemics and other cross-border threats to the circulation of people and things within and into the internal market are foregrounded. Although attention to the social determinants of ill health remains important via prevention efforts, the rationale for EU action builds on Article 168 TFEU to facilitate the prioritisation of preparedness planning and response. As seen in, for example, *Pandemic Influenza Preparedness and Response Planning in the European Community*, this is aimed at ensuring the readiness and resilience of essential governance infrastructures in the face of emergencies.<sup>29</sup>

---

23 Decision No. 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC, OJ 2013 No. L293/1.

24 These are defined by Art. 3(g) Decision No. 1082/2013/EU on serious cross-border threats to health and repealing Decision No 2119/98/EC, OJ 2013 No. L293/1, as ‘a life-threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection’.

25 Recital 6 of the Preamble to Decision No. 1082/2013/EU on serious cross-border threats to health and repealing Decision No 2119/98/EC, OJ 2013 No. L293/1.

26 European Commission, ‘White Paper, Together for Health: A Strategic Approach for the EU 2008–2013’, COM(2007) 630 final.

27 *Ibid.*, p. 3.

28 *Ibid.*, p. 2 (emphasis added). The EC along with the other two pillars of the EU were integrated into a single structure and became simply ‘the’ EU with the coming into force of the Treaty of Lisbon on 1 December 2009.

29 European Commission, ‘Communication on pandemic influenza preparedness and response planning in the European Community’, COM(2005) 607 final.

Elsewhere, *rarer* major threats are prioritised as one of the main challenges to be addressed by *Together for Health*:

*pandemics, major physical and biological incidents and bioterrorism pose potential major threats to health. Climate change is causing new communicable disease patterns. It is a core part of the Community's role in health to coordinate and respond rapidly to health threats globally and to enhance the EC's [European Community's and now the EU's] and third countries' capacities to do so. This relates to the [European] Commission's overall strategic objective of Security.*<sup>30</sup>

More broadly *Together for Health* configures public health governance within and orders its priorities in accordance with the overarching goal of generating economic optimisation, growth and jobs. Indeed: 'This Strategy reinforces the importance of health in policies such as the Lisbon Strategy for Growth and Jobs, emphasising the links between health and economic prosperity'.<sup>31</sup> Moreover, a chief objective of *Together for Health* is that it 'supports the overall Europe 2020 strategy',<sup>32</sup> which 'aims to turn the EU into a smart, sustainable and inclusive economy promoting growth for all – one prerequisite of which is a population in good health'.<sup>33</sup> In other words, a wider function of the risk-based governance of public health is the production and public legitimation of a very specific vision of the EU's sociopolitical order as being based on that economy and in turn the project of European integration.<sup>34</sup>

## **B. Obscuring the Scope and Implications of EU Responsibility and Limiting Citizen Participation**

Using risk as the frame depoliticises and naturalises public health governance and (like any frame) shapes perceptions of what constitute relevant, effective and legitimate solutions to public health problems.<sup>35</sup> Abetted by the fact that most public health and healthcare infrastructures are (formally speaking) parts of Member State responsibilities, the frame obscures the true reach of EU power and responsibility and its normative implications. The main concern is that framing public health by risk distorts regulatory attention and resources towards addressing consequences instead of the social, political and economic causes of public health problems.<sup>36</sup> This abets the privileging of communicable diseases and especially *rarer* ones through efforts to ensure the preparedness of governance infrastructures in the face of cross-border public health emergencies. The privileging of communicable diseases also marginalises major and chronic diseases such as cancer, heart disease and obesity – the diseases which cause the vast majority of morbidities and mortalities<sup>37</sup> – and prevention efforts which address their underlying social determinants, including those of *other* (*rarer*) health threats

---

30 European Commission, 'Together for Health', COM(2007) 630 final, p. 3 (emphasis added).

31 *Ibid.*, p. 2.

32 'Health strategy', [http://ec.europa.eu/health/strategy/policy/index\\_en.htm](http://ec.europa.eu/health/strategy/policy/index_en.htm) (emphasis added).

33 *Ibid.* (emphasis added).

34 Black, 'The Emergence', note 14 above, 519.

35 F. Fischer, *Reframing Public Policy: Discursive Politics and Deliberative Practices* (Oxford: Oxford University Press, 2003); D. A. Schon and M. Rein, *Frame/Reflection: Toward the Resolution of Intractable Policy Controversies* (New York, NY: Basic Books, 1994). See further: Flear, note 1, Chapter 8.

36 See further: Flear, *Governing Public Health*, note 1 above, ch. 7.

37 For example, over 80% of deaths in the WHO Europe region are attributable to (generally non-communicable) major and chronic diseases, see R. Busse et al., *Tackling Chronic Disease in Europe* (World Health Organisation, 2010), p. 10.

such as pandemics. This distortion of attention and priorities also suggests that the fear of potential harm arising from such often highly uncertain (and because of that probably scarier) threats creates 'institutional risks' (such as to standing and reputation) that ensures their management is prioritised over that of far more likely 'societal risks' (threats or dangers to society).<sup>38</sup>

EU level governance also shapes the conditions for and legitimates the selection of interventions at the Member State level. The focus of risk-based governance on regulating dangers or threats to the circulation of people and things (i.e. regulating free movement) is a particular instance of security – and that favours security-oriented responses which are often placed in a zero-sum relationship with human rights and bioethics protections. Risk-based governance also responsabilises individuals and targets them for blame and regulation through particularly intrusive interventions including criminal law sanctions.<sup>39</sup> The history of public health demonstrates that it is individuals who are part of groups already the subject of social opprobrium, marginalisation and discrimination who are most likely to be targeted, and that includes itinerant groups<sup>40</sup> and those who have become associated with particular diseases, such as HIV/AIDS.<sup>41</sup> Given the absence of burdens on all these targeted interventions are likely to remain uncontested by the more general population. Moreover, the focus on managing public health emergencies means that magic bullet medical responses tend to be favoured over population level interventions which target root causes. For example, testing kits, vaccination and treatment administered by triage have been the dominant response to pandemic influenza and other rare and emerging diseases, rather than sustained prevention efforts which would improve preparedness and response in the long term.

Citizen participation in decision making is part of attempts to identify and correct distortions of regulatory priorities and enhance trust in risk-based governance. There are two notable attempts to include citizens in decision making in the EU's public health domain. The first example is impact assessment (IA), a tool that is aimed at integrating consideration of the implications of regulation and policy in relation to policy domains – including public health – and it '*takes into account input of a wide range of external stakeholders*, in line with the Commission's policy of transparency and openness towards other institutions and the civil society'.<sup>42</sup> IA is about '[g]athering opinions and information from interested parties [and] is an essential part of the policy-development process, *enhancing its transparency and ensuring that proposed policy is practically workable and legitimate from the point of view of stakeholders*'.<sup>43</sup> IA is part of the wider process of shaping the involvement of stakeholders and the definition of their 'stake' as well as what is 'at stake' within the framework of risk.

---

38 See Rothstein, Huber and Gaskell, 'A Theory of Risk Colonisation', note 13 above.

39 J. Montgomery, 'Medicalising Crime – Criminalising Health? The Role of Law', in C. A. Erin and S. Ost (eds.), *The Criminal Justice System and Health Care* (Oxford: Oxford University Press, 2007).

40 For instance: R. Bivens, "'The English Disease" or "Asian Rickets"? Medical Responses to Postcolonial Immigration' (2007) 81 *Bulletin of the History of Medicine* 533; L. Eichelberger, 'SARS and New York's Chinatown: The Politics of Risk and Blame During an Epidemic of Fear' (2007) 65 *Social Science & Medicine* 1284.

41 The initial prevalence of the disease amongst men who have sex with men gave rise to the syndrome's initial name (Gay-Related Immune Deficiency or GRID) and while the name changed and the link has faded, it has proven hard to dissolve, even as it increasingly affects immigrants from sub-Saharan Africa, another marginalised group. See further: D. F. Musto, 'Quarantine and the Problem of AIDS' (1986) 64 *Milbank Quarterly* 97.

42 European Commission, 'Impact Assessment Guidelines', SEC(2009) 92, p. 6.

43 European Commission, 'Impact Assessment Guidelines', SEC(2005)791, p. 9 (emphasis added).



The second example is the ‘dialogue and collaboration’ around risk in the context of public health, which is recognised as part of the ‘new challenges for risk assessment’, first underlined in *European Governance* (and noted again below).<sup>44</sup> A central concern is that ‘[p]ublic opinion has become more sceptical about the neutrality and effectiveness of science, and there is a growing call for more transparency’.<sup>45</sup> At the same time, emerging risks brought about by technological developments and rare diseases undermine the production of data and cause risk assessors to ‘adapt and apply appropriate tools to evaluate new risks’. In order to address ‘this increased complexity’, DG Santé (the relevant part of the Commission that was renamed from DG SANCO in 2014) has ‘initiated risk assessment dialogues’.<sup>46</sup> However, at the EU level, dialogue and communication in relation to risk assessment focuses on relating the views of relevant individuals – as with the first example, these are usually termed ‘stakeholders’ – to scientific and technical knowledge and expertise in order to ground risk-based decision making.<sup>47</sup>

### C. Key Underpinnings of Citizen Participation

The aforementioned distortions of regulatory priorities suggest that current attempts to identify and correct regulatory priorities as well as citizen participation in decision making are far from adequate. Part of the reason for the limited regulatory role for participation is the framing of public health as a matter of risk, which operates ‘top-down’ to obscure and limit the substance and stakes for citizen participation in decision making and the space for democratic politics. Another important constraint on citizen participation arises from the centrality and valorisation of scientific and technical knowledge and expertise to legal and regulatory decision making. The latter reflects an expert rationality – the ‘quasi-guardianship’ of scientific experts<sup>48</sup> – which although understandable, implicitly devalues and limits the scope and potential for and contribution of citizen participation in decision making. Although implied in the construction of a risk-based frame for governance, the centrality of scientific and technical knowledge and expertise in the public health domain is underscored by the following:

*When preparing its policy and proposals relating to consumer safety, public health and the environment, the Commission relies on independent Scientific Committees to provide it with sound scientific advice and draw its attention to new and emerging problems. The Scientific Committees can call on additional expertise from a pool of scientific advisors and a database of experts.*<sup>49</sup>

In other words, the framing of public health by risk establishes, configures and legitimates hierarchies and relationships between scientific and technical knowledge and expertise, governance and regulation, and citizens.

The limited regulatory role of citizen participation is also based upon particular (and not unrelated) rationales for the inclusion of citizens in and their capacity to contribute towards decision making. As with much legal and regulatory studies scholarship on participation in decision making, the two ex-

---

44 European Commission, ‘European Governance: A White Paper’, COM(2001) 428 final.

45 ‘New challenges for risk assessment’, [http://ec.europa.eu/health/dialogue\\_collaboration/policy/index\\_en.htm](http://ec.europa.eu/health/dialogue_collaboration/policy/index_en.htm)

46 Ibid.

47 Ibid.

48 R. A. Dahl, *Democracy and its Critics* (New Haven, CT: Yale University Press, 1989), p. 335.

49 ‘Scientific Committees’, [http://ec.europa.eu/health/scientific\\_committees/policy/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/policy/index_en.htm).

amples noted above focus on procedures which appear to provide opportunities for citizen participation, but which actually regulate citizens into providing public legitimation.<sup>50</sup> EU law provides some of the key underpinnings for participation: it is proclaimed as a core value in the EU's Treaties,<sup>51</sup> including in the European Citizens' Initiative (a transnational instrument of participatory democracy<sup>52</sup>), and inflected in the CFR.<sup>53</sup> These legal foundations have been bolstered by the Aarhus Convention<sup>54</sup> and its implementation in EU law, for instance.<sup>55</sup> The latter instrument focuses on supporting participation to address the environmental impacts of new technologies, and it is therefore of limited importance to public health as it does not deal with the wider causes of disease and infirmity.

Non-binding policy statements are even more important to the underpinnings of citizen participation. These statements focus more clearly on integrating participation within procedures for the EU's risk-based decision making and configuring it in relation to scientific and technical knowledge and expertise.<sup>56</sup> The most important policy statements include the aforementioned *European Governance*, which in 2001 called for openness and transparency in expert work and enhanced public participation. The latter is to be achieved predominantly through the consultation of stakeholders<sup>57</sup> in a process of science-based decision making (as in the above examples).<sup>58</sup> The central objective of these moves is to reinforce accountability, engender or restore public trust and confidence in expertise after crises such as those over BSE (bovine spongiform encephalopathy) and GMOs (genetically modified organisms), and to bolster the legitimacy of governance and in turn, the EU's integration project.<sup>59</sup> Like wider attempts to facilitate citizen involvement in the governance of life and science nationally and internationally<sup>60</sup> – including developing awareness of the relationship with the right to health<sup>61</sup> – the EU's approach focuses on areas of risk and scientific uncertainty and recognises the need to take societal concerns into account through the input of those who are affected by decision

---

50 For a review see: Flear and Pickersgill, 'Regulatory or Regulating Publics?', note 6 above.

51 For instance, democracy is referred to as a value in Art. 2 TEU and a right to participation in the democratic life of the EU in Art. 10(3) TEU.

52 Established by Art. 11(4) TEU and Art. 24(1) TFEU. See: J. Mendes, 'Participation and the Role of Law After Lisbon: A Legal View on Article 11 TEU' (2011) 48 *Common Market Law Review* 1849.

53 Specifically, Art. 25 'recognises and respects the rights of the elderly to lead a life of dignity and independence and to participate in social and cultural life' while Art. 26 'recognises and respects the right of persons with disabilities to benefit from measures designed to ensure their independence, social and occupational integration and participation in the life of the community' (both emphasis added).

54 Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, Aarhus, 25 June 1998, entered into force 30 October 2001, 2161 UNTS 447.

55 For example: Council Decision 2005/370/EC of 17 February 2005 on the conclusion, on behalf of the European Community, of the Convention on access to information, public participation in decision-making and access to justice in environmental matters, OJ 2005 No. L124/1.

56 For discussion, see: U. Felt et al., *Taking European Knowledge Society Seriously: Report of the Expert Group on Science and Governance* (Luxembourg: Office for Official Publications of the European Communities, 2007), p. 52.

57 European Commission, 'Towards a Reinforced Culture of Consultation and Dialogue – General Principles and Minimum Standards for Consultation of Interested Parties by the Commission', COM(2002) 704 final.

58 European Commission, 'European Governance: A White Paper', COM(2001) 428 final, p. 8.

59 See, relatedly: G. Sundqvist, 'Recovery in the Acid Rain Story: Transparency and Credibility in Science-Based Environmental Regulation' (2003) 5 *Journal of Environmental Policy and Planning* 57.

60 For discussion, see: H. Gottweis, 'Participation and the New Governance of Life' (2008) 3 *BioSocieties* 265.

61 H. Potts, *Participation and the Right to the Highest Attainable Standard of Health* (Essex: University of Essex Human Rights Centre, 2009).

making which cannot be based on science alone. However, as the details of the policy reveal, participation has a limited regulatory role.

Another key document, *Science and Society Action Plan*,<sup>62</sup> contains similar themes to those apparent within *European Governance* and related documents.<sup>63</sup> Supported by Public Understanding of Science (PUS) techniques which actively seek to measure public opinion and knowledge,<sup>64</sup> such as the Eurobarometer,<sup>65</sup> this document works to clarify citizen/science relations in the EU and their configuration to decision making. A related technique is public consultation questionnaires, for instance through the *Stakeholder Consultation on Strengthening European Union Preparedness on Pandemic Influenza*.<sup>66</sup> These kinds of techniques are used to produce statistics and reports on strengthening governance, but they also invoke citizens, their understanding of public health science, and therefore the appropriate relationship between citizens and governance. So-called 'absent presences',<sup>67</sup> citizens are represented and imagined by EU actors so as to provide a democratic basis for their decisions. As such, the focus is on communication efforts, especially through the promotion of scientific education and culture, public awareness and the development of responsible policies which win wider confidence in decisions. Together, these construct a 'deficit model' within which participation is a means to further the much needed education of citizens who are deficient in their knowledge about science based issues (like public health).<sup>68</sup>

The 'deficit model' devalues the knowledge and expertise possessed by the subjects of its regulatory interventions and governance – the 'governed' – marginalising it and their role in decision making. The model also ignores how individuals come to know things in different ways, possess different kinds of knowledge and expertise,<sup>69</sup> and are reflexively aware of limitations in their ability to understand, which they may actively seek to address.<sup>70</sup> In sum, the model reflects and instils a very particu-

62 European Commission, 'Science and Society Action Plan', COM(2001) 714. See also: European Commission, 'Staff Working Paper. Science, Society and the Citizen in Europe', SEC(2000) 1973; European Commission, 'Science and Technology, the Key to Europe's Future: Guidelines for Future European Union Policy to Support Research', COM(2004) 353 final.

63 For example: European Commission, 'Life Sciences and Biotechnology: A Strategy for Europe', COM(2002) 27 final; European Commission, 'Promoting the Competitive Environment for the Industrial Activities Based on Biotechnology Within the Community', SEC(91) 629 final. See also: European Commission, 'Working Together for Growth and Jobs. A New Start for the Lisbon Strategy', COM(2005) 24 final.

64 J. Lezain and L. Soneryd, 'Consulting Citizens: Technologies of Elicitation and the Mobility of Publics' (2007) 16 *Public Understanding of Science* 279.

65 For example, on European attitudes to pandemic planning see: 'Influenza H1N1', [http://ec.europa.eu/health/communicable\\_diseases/diseases/influenza/h1n1/docs/eurobarometer\\_summary\\_20100224.pdf](http://ec.europa.eu/health/communicable_diseases/diseases/influenza/h1n1/docs/eurobarometer_summary_20100224.pdf). See more generally: European Commission, 'Europeans, Science and Technology' (Special Eurobarometer 154, December 2001); European Commission, 'Social Values, Science and Technology' (Special Eurobarometer 225, June 2005).

66 See 'Stakeholder Consultation on Strengthening European Union Preparedness on Pandemic Influenza', [http://ec.europa.eu/health/preparedness\\_response/consultations/preparedness\\_cons\\_01\\_en.htm](http://ec.europa.eu/health/preparedness_response/consultations/preparedness_cons_01_en.htm).

67 Felt et al., *Taking European Knowledge Society Seriously*, note 56 above, p. 58.

68 The idea of the 'deficit model' was introduced in ch. 1. Some of the same points and references are repeated here. See A. Irwin and B. Wynne (eds.), *Misunderstanding Science? The Public Reconstruction of Science and Technology* (Cambridge: Cambridge University Press, 1996).

69 A. Irwin and M. Michael, *Science, Social Theory, and Public Knowledge* (Maidenhead: Open University Press, 2003); M. Leach, I. Scoones and B. Wynne (eds.), *Science and Citizens: Globalisation and the Challenge of Engagement* (London: Zed Books, 2005).

70 A. Irwin, *Citizen Science: A Study of People, Expertise, and Sustainable Development* (London: Routledge, 1995); R. Lidskog, 'Scientised Citizens and Democratized Science: Re-Assessing the Expert-Lay Divide' (2008) 11 *Journal of Risk Re-*

lar public rationality in policy as a complement to the dominant expert rationality, and together they serve to keep citizens and (the provision of knowledge to) decision making at a distance.<sup>71</sup>

Overall, the focus is on harnessing scientific and technical knowledge and expertise and therefore privileging those voices in decision making and especially in decisions on how issues are framed. Citizen participation can, therefore, be chiefly understood as a technique and support for the public legitimation of risk-based governance. A central function of citizen participation is to build trust, quiet contestation and mediate the boundaries of responsibility and accountability for failure in respect of the governance of public health.<sup>72</sup>

### III. Reframing EU Public Health Governance as a Matter of EU Citizenship

#### A. Additional Pitfalls of Risk Governance for Participation and the Potential for 'Bottom-Up' Engagement

In the following I highlight the potential for and value of 'bottom-up' engagement,<sup>73</sup> before turning to outline the proposal to strengthen citizen participation and public health governance that the discussion in this chapter has been working towards. A key inspiration for the proposal is the idea that, as Foucault pointed out, governance does not only function 'top-down' but also produces 'biopolitics',<sup>74</sup> that is, an arena in which citizens can demand and contest decision making. STS, sociology and anthropology have built on this insight and developed a growing cluster of terms – 'moral pioneers',<sup>75</sup> 'genetic citizens',<sup>76</sup> 'biological citizenship',<sup>77</sup> and 'therapeutic citizens'<sup>78</sup> – which together underscore how people come to know and understand themselves and relate to others through knowledge of their biological and medical risk status. In relation to public health problems, the groups which can harness their common cause and articulate this position through human rights linked to bioethics – and which comprise citizens understood as 'the governed' – include those with underlying medical conditions, limited access to education and economic resources, pregnant women, children and itinerants. Another group is non-EU citizens residing in Europe (including undocumented migrants), a large group which often has difficulty accessing health services and health insurance and which tends to experience more health problems than 'regular' EU citizens.

---

search 69.

71 A. Irwin 'The Politics of Talk: Come to Terms with the "New" Scientific Governance' (2006) 36 *Social Studies of Science* 299.

72 See Flear, *Governing Public Health*, note 1 above, ch. 1, fn. 15, citing Flear and Pickersgill, 'Regulatory or Regulating Publics?', note 6 above.

73 Flear and Pickersgill, 'Regulatory or Regulating Publics?', note 6 above.

74 See in particular: M. Foucault, *The Birth of Biopolitics: Lectures at the Collège de France, 1978–1979* (London: Palgrave Macmillan, 2008). Also see: T. Lemke, *Biopolitics: An Advanced Introduction* (New York, NY: New York University Press, 2013).

75 R. Rapp, *Testing Women, Testing the Fetus: The Social Impact of Amniocentesis in America* (London: Routledge, 2000).

76 D. Heath, R. Rapp and K.-S. Taussig, 'Genetic Citizenship', in D. Night and J. Vincent (eds.), *A Companion to the Anthropology of Politics* (Oxford: Blackwell Publishing, 2004).

77 A. Petryna, *Life Exposed: Biological Citizens After Chernobyl* (Princeton, NJ: Princeton University Press, 2002); N. Rose and C. Novas, 'Biological Citizenship', in A. Ong and S. Collier (eds.), *Global Assemblages: Technology, Politics, and Ethics as Anthropological Problems* (Oxford: Blackwell Publishing, 2005). Cf. J. Biehl, *Will to Live: AIDS Therapies and the Politics of Survival* (Princeton, NJ: Princeton University Press, 2007).

78 V.-K. Nguyen, 'Antiretroviral Globalism, Biopolitics, and Therapeutic Citizenship', in A. Ong and S. Collier (eds.), *Global Assemblages: Technology, Politics, and Ethics as Anthropological Problems* (Oxford: Blackwell Publishing, 2005).

A key insight from the cognate disciplines is that although citizens might not be able to use or understand particular scientific and technical details, since those details are produced and articulated within broader frames, citizens can nevertheless participate as laypeople in relation to them.<sup>79</sup> In other words, not only can citizens contribute towards discussions on framing by risk,<sup>80</sup> they can contribute towards reflection on how those discussions should be reframed,<sup>81</sup> such as by querying the purpose of risk governance, whom it hurts, whom it benefits, and how we might come to understand these situations.<sup>82</sup> Although the current institutionalisation of citizen participation in EU governance might help explain the public's alienation from regulatory processes,<sup>83</sup> risk can provide the basis for mobilisation and participation.<sup>84</sup> Indeed, implicit in the above cluster of terms is the recognition that citizens are increasingly aware of their vulnerability in the face of risk (including dangers or threats produced by decisions about how to regulate) and demonstrate 'biosociality'<sup>85</sup> by working together in order to generate the 'politics of life itself'<sup>86</sup> and reshape and even reframe governance so that it addresses their concerns.<sup>87</sup>

However, the discourses that constitute governance (such as human rights and bioethics) have received little attention in STS and related scholarship as avenues or platforms for prompting, encouraging and powering 'bottom-up' engagement by citizens and reframing concerns as matters of citizenship. Much discussion in that scholarship also overlooks how participation can be stymied and its contribution of valuable supplementary knowledge to decision making frustrated by the risk governance process itself. In particular, as explained by Power, within risk-based governance, accountability has come to be linked with organisation in a single logic through which democratic ideals 'are *increasingly positioned* within ideals for good governance of the risk analysis process'.<sup>88</sup> Consequently, techniques for accountability such as participation become part of a broader process of rendering organisations auditable and inspectable in that they 'are *increasingly framed* as an organisational strategy to manage public expectations'.<sup>89</sup> Indeed, public perceptions are a source of risk, and so risk

---

79 B. Wynne, 'Uncertainty and Environmental Learning: Reconceiving Science and Policy in the Preventive Paradigm' (1992) 2 *Global Environmental Change* 111.

80 B. Wynne, 'Risk as a Globalising "Democratic" Discourse? Framing Subjects and Citizens', in M. Leach, I. Scoones and B. Wynne (eds.), *Science and Citizens: Globalisation and the Challenge of Engagement* (London: Zed Books, 2005).

81 F. Fischer, *Reframing Public Policy: Discursive Politics and Deliberative Practices* (Oxford: Oxford University Press, 2003).

82 S. Jasanoff, 'Technologies of Humility: Citizen Participation in Governing Science' (2003) 41 *Minerva* 223. For discussion see: M. Kusch, 'Towards a Political Philosophy of Risk', in T. Lewens (ed.), *Risk: Philosophical Perspectives* (London: Routledge, 2007).

83 B. Wynne, 'Creating Public Alienation: Expert Cultures of Risk and Ethics on GMOs' (2001) 10 *Science as Culture* 445.

84 In relation to biomedicine see S. Epstein, *Impure Science* (Berkeley, CA: University of California Press, 1996). See generally: U. Beck, *World at Risk* (Cambridge: Polity Press, 2008); R. Löfstedt, *Risk Management in Post-Trust Societies* (London, Palgrave Macmillan, 2005); O. Renn, *Risk Governance: Coping with Uncertainty in a Complex World* (London: Earthscan, 2008).

85 P. Rabinow, *Essays on the Anthropology of Reason* (Princeton, NJ: Princeton University Press, 1996); S. Gibbon and C. Novas (eds.), *Biosocialities, Genetics and the Social Sciences* (London: Routledge, 2007).

86 N. Rose, *The Politics of Life Itself: Biomedicine, Power and Subjectivity in the 21st Century* (Princeton, NJ: Princeton University Press, 2007).

87 R. Doubleday and B. Wynne, 'Despotism and Democracy in the United Kingdom: Experiments in Reframing Citizenship', in S. Jasanoff (ed.), *Reframing Rights: Bioconstitutionalism in the Genetic Age* (Cambridge, MA: MIT Press, 2011).

88 M. Power, *Organised Uncertainty* (Oxford: Oxford University Press, 2007), p. 20 (emphasis added).

89 *Ibid.*, pp. 20–21 (emphasis added).

management is partly an exercise in governing ‘*unruly perceptions*’ and maintaining the ‘*production of legitimacy in the face of these perceptions*’.<sup>90</sup> In short, the logic of accountability and organisation helps to maintain the instrumentalisation of citizen participation as a technique of legitimation in risk-based governance.

## **B. The Potential of Human Rights and Bioethics**

I suggest that human rights and bioethics – two key components of citizenship and important regulatory discourses – can be used to animate ‘bottom-up’ engagement by citizens which highlights the distortions of governance priorities or ‘societal risks’ outlined above (in section two). These distortions or risks constitute supplementary knowledge which is all too easily missed or under acknowledged by risk-based public health governance. What makes human rights and bioethics so useful is their capacity to transform those (un or under-addressed) ‘societal risks’ into ‘institutional risks’ (a key preoccupation of governance noted in section two) which need to be addressed in order to re-legitimate EU governance and the European integration project. This proposal therefore leverages the EU’s legitimation needs and resists the instrumentalisation of citizen participation in the current design of risk-based governance.

Human rights law is obviously closely related to citizenship and it is foundational to the EU’s constitutional legal order. Human rights has been very successful as a body of law and as a broader discourse in demands for and contestation of social justice issues,<sup>91</sup> including in the EU.<sup>92</sup> More particularly, the right to health is clearly implicated in Article 35 CFR.<sup>93</sup> The meaning and implications of this provision are awaiting judicial interpretation, which only adds to its indeterminacy and discursive potential. Indeed, Article 35 might be developed in light of the WHO’s definition of health as a state of complete physical, mental and social wellbeing and not merely the absence of infirmity,<sup>94</sup> as well as other right-to-health provisions under human rights law, such as Articles 11 and 13 European Social Charter.<sup>95</sup>

Article 13 provides that ‘*anyone without adequate resources has the right to social and medical assistance*’ (emphasis added). Article 11 provides that ‘*everyone has the right to benefit from any measures enabling him to enjoy the highest standard of health attainable*’ including through measures which ‘*remove as far as possible the causes of ill-health*’ and ‘*prevent as far as possible epidemic, endemic and other diseases, as well as accidents*’ (emphasis added). Developed in this light, Article 35 could in turn shape the interpretation of the respective requirements to ensure a high level of human health protection as under Article 9 TFEU and reflected in Article 168(1) TFEU (which Article 35 takes over). Shaping the interpretation of these provisions could be useful not just in adjudication, but also (and crucially) in wider and potentially more important attempts to demand and con-

---

<sup>90</sup> *Ibid.*, p. 21 (emphasis added).

<sup>91</sup> W. Brown, *States of Injury* (Princeton, NJ: Princeton University Press, 1995); W. Brown, ‘Suffering Rights as Paradoxes’ (2000) 7 *Constellations* 230.

<sup>92</sup> For instance for lesbian, gay and transgender citizens. See: C. F. Stychin, *Governing Sexuality: The Changing Politics of Citizenship and Law Reform* (Oxford: Hart Publishing, 2003), ch. 1 ‘The Sexual Citizen’.

<sup>93</sup> For discussion see: T. Hervey and J. McHale, ‘Article 35’, in S. Peers et al. (eds.), *The EU Charter of Fundamental Rights: A Commentary* (Oxford: Hart Publishing, 2015). See further: T. Murphy, *Health and Human Rights* (Oxford: Hart Publishing, 2013).

<sup>94</sup> Constitution of the World Health Organisation, New York, 22 July 1946, entered into force 7 April 1948, 14 UNTS 185.

<sup>95</sup> European Social Charter (Revised), Strasbourg, 3 May 1996, entered into force 1 July 1999, 2151 UNTS 277, ETS 163.

test decision making, to address the distortions of governance outlined above.<sup>96</sup> Indeed, these provisions could be developed and used in order to campaign for further efforts to address the social determinants of ill health. For example, in particular to contribute towards lowering the incidence of major and chronic diseases and avoiding regulatory interventions which are discriminatory and/or which compound social stigma, marginalisation and discrimination.

To that end, human rights could be particularly useful when used in combination with bioethics. Bioethics (like citizen/science relations) became important in the EU's governance of public health and life after the regulatory crises of BSE and GMOs as a way of producing engagement and deliberative practices – a use which has been the subject of growing attention in STS<sup>97</sup> and in law.<sup>98</sup> Ethics is determined by Member State governments and experts, such as those comprising research ethics committees for clinical trials<sup>99</sup> or the European Group on Ethics in Science and New Technologies, which provides the European Commission with a comprehensive range of opinions on 'all areas of the application of science and technology'.<sup>100</sup> These opinions produce various exhortatory, persuasive and binding consequences,<sup>101</sup> such as support for controversial research funding.<sup>102</sup> In this light, the wider function of ethics is 'to ensure that the general public is kept properly informed'<sup>103</sup> and to 'keep the rapidly advancing progress in science in harmony with the ethical values of all Europeans'<sup>104</sup> – without which 'European citizenship cannot be established'.<sup>105</sup>

Bioethics is therefore an important regulatory and legitimating discourse which like human rights is implicated in the realisation of EU citizenship. In addition, bioethics can be leveraged by human rights to support participation. That is not simply because bioethics is increasingly linked to human rights, as seen in several international declarations.<sup>106</sup> Rather, as Ashcroft notes, an important potential consequence of the link between human rights and bioethics is the capacity of the former, when in the 'hands of activists, at least to disrupt [...] by *challenging the language, the types of problem recognised* [...] and the *working methods* of the public bioethics process. This might particularly be

96 T. Murphy, 'Repetition, Revolution, and Resonance', in T. Murphy (ed.), *New Technologies and Human Rights* (Oxford: Oxford University Press, 2009), p. 7.

97 A. Moore, 'Public Bioethics and Deliberative Democracy' (2010) 58 *Political Studies* 715.

98 J. Montgomery, 'Reflections on the Nature of Public Ethics' (2013) 22 *Cambridge Quarterly of Healthcare Ethics* 9. See also, the discussion on stewardship below.

99 Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, OJ 2001 No. L121/34.

100 Commission Decision 2005/383/EC of 11 May 2005 on the renewal of the mandate of the European Group on Ethics in Science and New Technologies, 2005 OJ No. L127/17.

101 M. Tallacchini, 'Governing by Values. EU Ethics: Soft Tool, Hard Effects' (2009) 47 *Minerva* 281

102 For example: European Group on Ethics in Science and New Technologies, *Opinion 10 on Ethical aspects of the 5th Research Framework Programme* (11 December 1997); and *Opinion 22 on the Ethics Review of hESC FP7 Research Projects* (13 July 2007).

103 'Mandate 1991–1997', [http://ec.europa.eu/bepa/european-group-ethics/archive-mandates/mandate-1991-1997/index\\_en.htm](http://ec.europa.eu/bepa/european-group-ethics/archive-mandates/mandate-1991-1997/index_en.htm) (emphasis added).

104 Felt et al., *Taking European Knowledge Society Seriously*, note 56 above, p. 49 (emphasis added).

105 Ibid., p. 80, citing [http://ec.europa.eu/european\\_group\\_ethics/archive/1991\\_1997/bilan\\_en.htm](http://ec.europa.eu/european_group_ethics/archive/1991_1997/bilan_en.htm) (emphasis added).

106 For instance, the UN Educational, Scientific and Cultural Organization (UNESCO), 'Universal Declaration on Bioethics and Human Rights' (2005), and in the European context in the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo Convention), Oviedo, 4 April 1997, entered into force 1 December 1999, ETS 164, and its Protocols.

the case where the challenge to bioethics comes from groups [such as those noted above] which have tried – and failed – to *challenge the policy consensus* by other methods'.<sup>107</sup>

The developing discourse on stewardship responsibility found in human rights-inflected public bioethics frameworks provides further encouragement for the potential of the link between human rights and bioethics to support citizen participation that underlines and prompts efforts to address the distortions of risk-based public health governance. For example, the WHO's version of stewardship in *World Health Report 2000* directs attention towards the social determinants of health through prevention and efforts to address epidemic, endemic and other diseases by reference to the importance of: '*improving overall levels of population health [...and] objectives [which] are likely to be framed in terms of equity, coverage, access, quality, and patients' rights*'.<sup>108</sup> Another version of stewardship responsibility is found in the 2007 report of the Nuffield Council on Bioethics, '*Public Health: Ethical Issues*'.<sup>109</sup> Three of Nuffield's authors, Baldwin, Brownsword and Schmidt, note how stewardship means '*liberal states have responsibilities to look after important needs of people both individually and collectively. Therefore, states are stewards both to individual people [...] and to the population as a whole*'.<sup>110</sup> Stewardship is not solely about *state* responsibilities. Brownsword notes that what he calls '*super-stewardship*' is '*a significant item of unfinished business*'<sup>111</sup> – and this points towards the responsibilities of international and supranational organisations such as the EU for individuals and the whole population.<sup>112</sup>

Nevertheless, human rights and bioethics might also present problems for the discursive strategy for enhancing citizen participation. A key pitfall of human rights and bioethics which could abet the focus on individual responsibility and self-management in risk-based governance, is their tendency to focus on the individual and obscure the wider social sources of vulnerability and the importance of overall health protection.<sup>113</sup> These concerns underline the importance of reflecting on the limits of human rights and bioethics in order to mitigate them. It might also be objected that the participatory strategy proposed in this chapter risks further compromising public health by facilitating the extension of EU market-oriented norms into public health as a formally non-market domain of collective provision. Yet, since the EU is already involved in public health, the main problem is reshaping its priorities so that they are more balanced rather than more extensive – and human rights and bioethics promise to pique and mobilise citizen interest and discussion on public health.<sup>114</sup> Human rights and bioethics can reframe governance as a matter of citizenship and a space for democratic contestation of

---

107 R. Ashcroft, 'Could Human Rights Supersede Bioethics?' (2010) 10 *Human Rights Law Review* 639 at 645 (emphasis added). This builds on T. Murphy and N. Whitty, 'Is Human Rights Prepared? Risk, Rights and Public Health Emergencies' (2009) 17 *Medical Law Review* 219.

108 'Governance', <http://www.who.int/healthsystems/topics/stewardship/en/index.html>.

109 *Public Health: Ethical Issues* (London: Nuffield Council on Bioethics, 2007).

110 T. Baldwin, R. Brownsword and H. Schmidt, 'Stewardship, Paternalism and Public Health: Further Thoughts' (2009) 2 *Public Health Ethics* 113 at 115 (emphasis added), citing *ibid.*, p. 25.

111 R. Brownsword, 'So What Does the World Need Now? Reflections on Regulating Technologies', in R. Brownsword and K. Yeung (eds.), *Regulating Technologies: Legal Futures, Regulatory Frames and Technological Fixes* (Oxford: Hart Publishing, 2008), p. 47.

112 See further: M. L. Flear (ed.), 'Papers From "A Symposium with Professor Roger Brownsword: Super-Stewardship in the Context of Public Health"' (2011) 62 *Northern Ireland Legal Quarterly*.

113 In relation to human rights see the references to Brown, *States of Injury*, note 91 above, and for bioethics see Ashcroft, 'Could Human Rights', note 107 above, 645.

114 In this vein see N. Fairclough, *Language and Power* (London: Routledge, 2001).



responsibilities, such as the requirements to ensure a high level of health protection noted above.<sup>115</sup> Reframing widens the ‘way in’ for participation in decision making provided by references to participation and democracy in *European Governance* (which sensitised governance to the potential for citizen participation as a generator of views and not solely as a technique of legitimation (despite that being its key function)), the EU’s constitutional order, human rights law and discourse. Vitality, reframing promises to produce supplementary knowledge, i.e. on the distortions of EU governance priorities.

Take-up of this knowledge in decision making is facilitated by two important aspects of human rights and bioethics. The first is that these discourses are already part of the language of EU governance and for that reason might persuade and convince those formally charged with or influential in decision making.<sup>116</sup> Arguments and claims framed in terms of human rights and bioethics might be particularly compelling for a related reason. Since human rights and bioethics are also key legitimating discourses for EU public health governance,<sup>117</sup> articulating arguments through those discourses helps to transform the distortions of public health governance or ‘societal risks’ into key ‘institutional risks’ to the EU’s standing and reputation. These in turn need to be addressed, since they threaten to *delegitimize* the EU and the integration project. The latter builds on how participation tends to be used as a legitimating technique to impel renewed attempts to integrate citizen demands and knowledge into decision making – but as part of ongoing attempts to ensure the *relegitimation* of governance and the overall project of integration.

#### IV. Conclusion

By reframing EU public health governance as a matter of citizenship via human rights and bioethics, a fuller impression of the scope of EU power and responsibility can be brought into view. In particular, developing the content and meaning of Article 35 CFR and using it in combination with bioethics to reflect on EU governance (as seen in the developing notion of stewardship) could help in public querying of compliance with the requirement to ensure a high level of health protection found in that provision, as well as under Articles 9 and 168(1) TFEU (which is taken over by Article 35). Through such querying human rights and bioethics could therefore help citizens contest the distortion of public health priorities engendered by framing governance as a matter of risk. Overall, reframing public health as a matter of citizenship through human rights and bioethics could help to ensure the EU is held to account and fulfils its responsibility to ensure equal protection, justice and equity for all. As such human rights and bioethics can help citizens align EU governance more closely to their concerns and demands within the current division of competence between the EU and its Member States. That would in turn assist in the ongoing development of the European integration project in ways which live up to the democratic potential of EU citizenship.

---

115 For discussion see J. Habermas, *The Crisis of the European Union: A Response* (Cambridge: Polity Press, 2012). See further: N. Fraser, ‘Transnationalising the Public Sphere: On the Legitimacy and Efficacy of Public Opinion in a Post-Westphalian World’, in S. Benhabib, I. Shapiro and D. Petranović (eds.), *Identities, Affiliations and Allegiances* (Cambridge: Cambridge University Press, 2007).

116 M. Edelman, *Political Language: Words That Succeed and Policies That Fail* (London: Academic Press, 1973).

117 A point I make in greater detail in Flear, *Governing Public Health*, note 1 above.