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REGULATORY OR REGULATING PUBLICS? THE EUROPEAN UNION'S REGULATION OF EMERGING HEALTH TECHNOLOGIES AND CITIZEN PARTICIPATION

MARK L. FLEAR[1]* AND MARTYN D. PICKERSGILL[2]*

[1]*Lecturer in Law, School of Law, Queen's University Belfast, 28 University Square, Belfast BT7 1NN, UK and Member of the NI DNA Database Governance Board*
m.flear@qub.ac.uk
[2]*Wellcome Trust Senior Research Fellow in Biomedical Ethics, Centre for Population Health Sciences, University of Edinburgh Medical School, Medical School, Teviot Place, Edinburgh EH8 9AG, UK*
martyn.pickersgill@ed.ac.uk

ABSTRACT

'Citizen participation' includes various participatory techniques and is frequently viewed as an unproblematic and important social good when used as part of the regulation of the innovation and implementation of science and technology. This is perhaps especially evident in debates around 'anticipatory governance' or 'upstream engagement'. Here, we interrogate this thesis using the example of the European Union's regulation of emerging health technologies (such as nanotechnology). In this case, citizen participation in regulatory debate is concerned with innovative objects for medical application that are considered to be emergent or not yet concrete. Through synthesising insights from law, regulatory studies, critical theory, and science and technology studies, we seek to cast new light on the promises, paradoxes, and pitfalls of citizen participation as a tool or technology of regulation in itself. As such we aim to generate a new vantage point from which to view the values and

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sociotechnical imaginaries that are both 'designed-in' and 'designed-out' of citizen participation. In so doing, we show not only how publics (do not) regulate technologies, but also how citizens themselves are regulated through the techniques of participation.

Keywords: Participation, Law, Regulation, Science, Technology

I. INTRODUCTION

The place, role, and impact of individuals and communities—together, 'the public'—within science, technology, and engineering has, it seems, never before been more obvious, or contested.[1] Citizen or public participation[2] is a tool of governance which includes various techniques aimed at incorporating the perspectives of publics within science policy and regulation,[3] and/or to inform processes of innovation. Many view participation as an unproblematic and important social good when used as part of the regulation of the innovation and implementation of science and technology. Think-tanks like Demos, for instance, have done much to stimulate and promote debates around anticipatory governance and, relatedly, upstream engagement.[4] Yet, other commentators have been more critical of such ventures. In particular, some scientists (and bioethicists) have been resistant to the 'democratisation' of policy and research, and a number of social scientists have been vocal in their critiques of the scope and limits of participatory techniques.[5]

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[1] Eg Royal Society and the Royal Academy of Engineering, *Nanoscience and Nanotechnologies: Opportunities and Uncertainties* (Royal Society, London 2004), Ch 7 'Stakeholder and Public Dialogue'.

[2] Like many of the actors and institutions involved, we use these terms interchangeably. For more detail on forms of participation and engagement, and its relation to scientific governance, see: A Irwin, 'The Politics of Talk: Coming to Terms with the 'New' Scientific Governance' (2006) 36 Social Studies of Science 299.

[3] Black's definition of regulation is 'the intentional use of authority to affect behaviour of a different party according to set standards, involving instruments of information-gathering and behaviour modification' (J Black, 'Critical Reflections on Regulation' (2002) 27 Australian Journal of Legal Philosophy 1). This understanding of regulation includes technologies as well as 'hard law', 'soft law', social norms, and the market. See further: R Baldwin, M Cave, and M Lodge, 'Regulation, the Field and the Developing Agenda' in R Baldwin, M Cave and M Lodge (eds), *The Oxford Handbook on Regulation* (Oxford University Press, Oxford 2011).

[4] Eg J Wilsdon and R Willis, *See-Through Science: Why Public Engagement Needs to Move Upstream* (Demos, London 2004).

[5] As we will discuss later in the article, though see: J Schummer 'Identifying Ethical Issues in Nanotechnologies' in H ten Have (ed), *Nanotechnologies, Ethics and Politics* (UNESCO, Paris 2007), 81, cited in R Brownsword, *Rights, Regulation and the Technological Revolution* (Oxford University Press, Oxford 2008), 121, and with further discussion of definition and

In this article, we consider these issues from a somewhat different (but nevertheless related) vantage point. Drawing on insights from law, regulatory studies, critical theory, and science and technology studies (STS), we explore the ways in which participatory techniques can be understood as technologies themselves (an understanding that brings attention to the techniques and practices that enable symbolic or material change).[6] Specifically, we draw attention to how attempts to regulate in the face of uncertain scientific knowledge provide the conditions of possibility for participation. As such, we query the function of participation—what does the technology do?—as well as the norms, values, perspectives, and ultimately, the actual and imagined users that are 'built into' and privileged by it. In other words, we are interested both in how publics[7] regulate technologies, and how citizens themselves are regulated through technologies of participation.[8]

Our case study for this analysis is the European Union's (EU's) regulation of emerging health technologies, especially nanotechnology (i.e. its nanoregulation).[9] One, narrow, definition of nanotechnology is

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spheres of application, 120–2; J Tait 'Upstream Engagement and the Governance of Science' (2009) 10 EMBO Reports S18–22.

[6] For a discussion of 'technology' understood in a broad sense, see M Pickersgill, 'Sociotechnical Innovation in Mental Health: Articulating Complexity' in ML Flear and others (eds), *European Law and New Health Technologies* (Oxford University Press, Oxford 2013 (Forthcoming)).

[7] By 'publics', we mean all individuals who are not formal policy actors in the regulation of health technologies, nor scientists/engineers involved in the processes of innovation being regulated. We refer to 'publics', in the plural, rather than 'the public', in the singular, in order to underscore the plurality of cultures within and between countries. See: H Dietrich and R Schibeci, 'Beyond Public Perceptions of Gene Technology: Community Participation in Public Policy in Australia' (2003) 12 Public Understanding of Science 381.

[8] Cf ML Flear, 'The EU's Biopolitical Governance of Advanced Therapy Medicinal Products' (2009) 16 (1) Maastricht Journal of European and Comparative Law 113. See further: ML Flear and S Ramshaw (eds), *Symposium: New Technologies, European Law and Citizens* (Special Issue) (2009) 16 (1) Maastricht Journal of European and Comparative Law.

[9] For discussion of this emerging area, see: B Dorbeck-Jung, DM Bowman, and G Van Calster (eds), *Governing Nanomedicine: Lessons from Within, and For, the EU Medical Technology Regulatory Framework* (Special Issue) (2011) 33(2) Law and Policy (especially: C Altenstetter, 'Medical Device Regulation and Nanotechnologies: Determining the Role of Patient Safety Concerns in Policymaking' (2011) 33(2) Law and Policy 227; B Dorbeck-Jung and N Chowdhury, 'Is the European Medical Products Authorisation Regulation Equipped to Cope with the Challenges of Nanomedicines?' (2011) 33 (2) Law and Policy 276); B Dorbeck-Jung, 'The Governance of Therapeutic Nanoproducts in the European Union—A Model for New Health Technology Regulation?' in ML Flear and others (eds), *European Law and New Health Technologies* (Oxford University Press, Oxford 2013 (Forthcoming)); J D'Silva and DM Bowman, *The Legal Regulation of Nanotechnologies* (Special Issue) (2011) 2(3) European Journal of Law and Technology. <http://ejlt.org/>; M Lee, 'Risk and Beyond: EU Regulation of

'the investigation and manipulation of material objects in the 1–100 nanometer range so as to explore novel properties and develop new devices and functionalities that essentially depend on the 1–100 nanometer range'.[10] These potentially transformative capabilities are now being applied in a wide range of contexts, including energy, the environment, information, and communication technology, and in the medical sphere. In relation to the latter, the European Medicines Agency, for instance, defines nanomedicine as 'the application of nanotechnology in view of making a medical diagnosis or treating or preventing diseases. It exploits the improved and often novel physical, chemical and biological properties of materials at nanometre scale'.[11]

Nano-enabled medical technologies that are emergent or not yet concrete are highlighted in parts of our discussion because they tend to be stressed in EU nanoregulation as an example of a notable field of application. The most likely reason for this is the quotidian use and (revolutionary) potential of nanotechnology in the medical context (highly pertinent to individuals and governments, perhaps especially in post-industrial democratic societies). As such, nanomedicine comprises highly resonant innovative objects (i.e. tools or techniques that can be regarded as novel) and practices (i.e. new scientific disciplines or research agendas) in the public imagination.[12] This makes nanomedicine a particularly useful example to pique citizen interest in and engagement with regulatory decision-making. Forging regulation for nanoscience and technology has been undermined by the ambiguity of research and development in this area. That is, the inherent scientific uncertainty about the degree and types of risks nanotechnologies pose, such as to vulnerable recipients/patients, as well as their potential, thwarts exclusive reliance on risk-based regulation that often aims to produce legitimate decisions by using science and focusing on the consequences for safety. This has produced a turn towards exercises in participation

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Nanotechnology' (2010) 35 European Law Review 799; JV McHale, 'Nanomedicine and the EU: Some Legal, Ethical and Regulatory Challenges' (2009) 16 (1) Maastricht Journal of European and Comparative Law 65.

[10] Schummer, above, n 5, 81. For further discussion of definition and spheres of application, see: Brownsword, above, n 5, 120–2.

[11] European Medicines Agency, 'Nanotechnology-based Medicinal Products for Human Use' Reflection Paper EMA/CHMP/79769/2006 (EMA, London 2006). Available at: <http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2010/01/WC500069728.pdf> (last accessed 2 May 2012). See further: European Commission, *Towards a European Strategy for Nanotechnology*, COM(2004) 338 final, 4; European Technology Platform, *Nanomedicine: Nanotechnology for Health* (November 2006); European Group on Ethics in Science and New Technologies (EGE), *Opinion on the Ethical Aspects of Nanomedicine* (Opinion No 21), 17 January 2007, para 2.2.

[12] For discussion, see: Dorbeck-Jung, 'Therapeutic Nanoproducts' above, n 9.

that seek to contribute towards regulation through the production of (procedurally if not substantively) legitimate decisions.

We do not attend further to the differences between nanotechnology and nanomedicine, in terms of the nature of the risk and uncertainty about their respective uses, nor do we examine the differences in their regulation. Instead, we focus on participation in the regulation of nanoscience and technology in general. Our reason is simple: as we go on to trace, it is at this broad level that the EU is currently involved, even as medical applications are stressed in the pertinent discourses. Nevertheless, participation in the EU's nanoregulation and its more general techno-regulation remain underexplored. This lack of attention is especially striking given the EU's increasingly active regulation of emerging and new health technologies, and its growing interest in fostering and governing innovation—including the science of nanotechnology (nanoscience), in the general field of health.[13] A focus on participation is especially timely given that the gathering pace of EU nanoregulation means participatory techniques are likely to be developed in the near future.[14]

Our paper, then, aims to underscore the extent to which, in general, public participation in the EU has been used more to legitimate regulation than to ensure the substantive involvement of citizens in the regulation of science and technology. In essence, participation is a technology to build trust and promote consumption in the marketplace, rather than regulate innovation. Indeed, and as we will later explore, we might speculate as to whether the design of participation—by privileging some kinds of expertise and voices over others—actually *decreases* the impact of citizens on regulation. Furthermore, it is possible that the design of participatory techniques and processes help to produce a mandate for innovation, by leveraging scientific uncertainty to impel innovation which will then reduce this. In this way, we can advance—and proffer some answers to—the question of whether citizens involved in EU participatory exercises are 'regulatory publics' (i.e. publics who can and do impact upon the regulation of science and technology), or whether they are themselves regulated.

Our analytic perspective is built through a variety of literatures, particularly within law, regulatory studies, and STS; accordingly, a broader aim for this article is to contribute to the developing dialogue between law and STS.[15] Such scholarship seeks to frustrate the demarcations

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[13] ML Flear, A-M Farrell, TK Hervey, and T Murphy (eds), *European Law and New Health Technologies* (Oxford University Press, Oxford 2013 (Forthcoming)).

[14] Dorbeck-Jung, 'Therapeutic Nanoproducts' above, n 9.

[15] See: J Abraham and H Lawton-Smith (eds), *Regulation of the Pharmaceutical Industry* (Palgrave, Basingstoke 2003); J Aronson, *Genetic Witness: Science, Law, and Controversy in the Making of DNA Profiling* (Rutgers University Press, Piscataway 2007); E Cloatre and MD Pickersgill (eds), *Technoscience,*

that may be made between law and science; these divisions serve to deny the normative content of technology and scientific knowledge, and potentially shield innovation from engagement by law.[16] We regard it as crucial that these insights be developed and circulated, given the common and potentially dangerous idea that law is unable to 'keep up' with technology—the so-called problem of 'pace' highlighted by Brownsword[17]—and which links to the potential for the 'rule of technology' as a means of regulating behaviour and social outcomes through design.[18]

In meeting our aims, in the next section we engage with and synthesise some key insights from law, regulatory studies, critical theory, and STS. In so doing, we hope to animate fresh debate about the scope, limits, and future of public participation at the level of the EU, while also providing a conceptual resource through which positions can be articulated.[19] From there, we go on to consider innovation and participation in the EU: what does this look like in general, and how does this play out for nanotechnology specifically? This sets the scene for a more in-depth analysis of public participation in nanotechnology; here, we examine the role played by future uses of nanotechnology, discourses of risk and uncertainty, and practices of 'educating' citizens, in ordering and constituting the machinery of participatory technologies—and thus how they regulate publics and science.

Law and Society: Interrogating the Nexus (Routledge, London 2013 (Forthcoming)); A Daemmrich, *Pharmacopolitics: Drug Regulation in the United States and Germany* (University of North Carolina Press, Chapel Hill 2006); R Hindmarsh and B Prainsack (eds), *Genetic Subjects: Global Governance of Forensic DNA Profiling and Databasing* (Cambridge University Press, Cambridge 2010); S Jasanoff (ed), *Reframing Rights: Bioconstitutionalism in the Genetic Age* (MIT Press, Cambridge, MA 2011); B Latour, *The Making of Law: An Ethnography of the Conseil d'Etat* (Polity, Cambridge 2009); C Lawless and A Faulkner (eds), *Material Worlds: Intersections of Law, Science, Technology and Society* (Wiley-Blackwell, Oxford 2012); M Lynch, SA Cole, and R McNally, *Truth Machine: The Contentious History of DNA Fingerprinting* (University of Chicago Press, Chicago 2008); S Parthasarathy, *Building Genetic Medicine: Breast Cancer, Technology, and the Comparative Politics of Health Care* (MIT Press, Cambridge, MA 2007); A Pottage and B Sherman, *Figures of Invention: A History of Modern Patent Law* (Oxford University Press, Oxford 2010).

[16] For discussion, see: T Murphy and N Whitty, 'Risk and Human Rights in UK Prison Governance' (2007) 47 British Journal of Criminology 798.

[17] See further: 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* (Hart Publishing, Oxford 2008).

[18] L Lessig, *Code: And Other Laws of Cyberspace* (Basic Books, New York 1999); R Brownsword, 'Code, Control and Choice: Why East is East and West is West' (2005) 25 Legal Studies 1; Brownsword, above, n 5.

[19] Cf P McNaghton, M Kearnes, and BE Wynne, 'Nanotechnology, Governance and Public Deliberation: What Role for the Social Sciences?' (2005) 27 Science Communication 268.

II. CONCEPTUAL APPROACH

The perceived risk of new scientific and technological developments is a central concern especially in relation to the EU, which has met with a crisis of public confidence and legitimacy[20] in the wake of high-profile regulatory failures such as the BSE[21] crisis of the 1990s. One corollary of this has been a proliferation of debate in regards to what regulation in cases of scientific risk and uncertainty should look like, and how it should be implemented.[22] Law and regulatory studies, with their focus on decision-making, are, of course, central to this debate, especially given renewed attention to the salience of the context of scientific uncertainty. This is highlighted in the influential academic analysis provided by Brownsword, who has argued that regulators 'need to tailor their interventions to the perceived risk profile presented by a particular technology'.[23] This involves determining such matters as when risk materialises (whether it is when the technology goes wrong or is abused—or works!); the degree of risk (low or high); the kind of harms or hazards to which risk pertains (physical, environmental, social, economic, moral, and political) and the potential for their ranking; and, finally, how risk relates to precaution (whether precaution occurs at risk assessment or somehow operates in risk management).[24] In short, the destabilised scientific foundations of decision-making around emerging technologies like nanotechnology present a problem for the production of a risk profile in that so much is unknown and uncertain, and there is little agreement on a range of issues—including how risks 'should be framed, which methodologies should be adopted, [and] which values prioritized'.[25]

Moreover, and as a crucial link to participation, with risk-based approaches undermined but nevertheless still central to the regulation of emergent technologies, such as nanotechnology, 'the legitimacy crisis becomes acute'.[26] In such cases, public participation is seen as a key way of achieving accountability and legitimacy.[27] Indeed,

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[20] For an overview, see: C Scott, 'Accountability in the Regulatory State' (2000) 27 Journal of Law and Society 38; F Scharpf, *Governing in Europe. Effective and Democratic?* (Oxford University Press, Oxford 1999); A Arnull and D Wincott, *Accountability and Legitimacy in the European Union* (Oxford University Press, Oxford 2002).

[21] That is, bovine spongiform encephalopathy.

[22] For discussion, see: M Everson and E Vos, 'The Scientification of Politics and the Politicisation of Science' in M Everson and E Vos (eds), *Uncertain Risks Regulated* (Routledge-Cavendish, Oxon 2009).

[23] Brownsword, above, n 5, 118.

[24] Ibid, 118–9.

[25] Ibid, 119–20.

[26] Ibid, 131.

[27] On the necessity of public engagement, see: DJ Fiorini, 'Citizen Participation and Environmental Risk: A Survey of Institutional Mechanisms' (1990) 15 Science, Technology & Human Values 226.

participation is noted as best occurring from the beginning of technological development. For Mandel, participation at an early stage in innovation when there is 'a high degree of uncertainty and a low degree of attachment to the status quo, can present a *unique opportunity to bring together diverse stakeholders to produce a collaborative governance system* rather than a resource-draining adversarial battle'.[28]

Nevertheless, irrespective of the precise rationalities[29] for participation, including the quelling of contestation through prefiguring what is 'at stake' in discussions, or some sort of input of knowledge and perspectives, early engagement is held to produce smarter regulation.[30] Consequently, there is concern for, as Brownsword puts it, the 'general features to be designed in[to]'[31] participation. Importantly, in the context of the 'bioethical triangle' underpinning regulation—an empowering human rights perspective, a largely restrictive and disempowering dignitarian perspective, and a pragmatic utilitarian perspective[32]—there is little possibility of substantive agreement, and even proceduralism can reach its limits.

Yet, there is a need to go further here by looking beyond formal proceduralism to explore how regulation in the context of uncertain scientific knowledge provides the conditions of possibility for, and impacts on the design of, participation. That said, public participation in risk regulation is thus not only an important means of steering EU activities and providing a framework for negotiating and governing uncertainty. Participation is also implicated in the fabrication of the boundaries of responsibility and

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[28] GN Mandel, 'Regulating Emerging Technologies' (2009) 1 Law, Innovation and Technology 75. Emphasis added. Cf Brownsword, above, n 5, 124 (who stresses the importance of approaching and addressing public concerns from the beginning of the development of nanotechnologies for medical application).

[29] Rose et al. describe this as 'a way of doing things that . . . [is] oriented to specific objectives and that . . . [reflects] on itself in characteristic ways': N Rose, P O'Malley, and M Valverde, 'Governmentality' (2006) 2 Annual Review of Law and Social Science 83, 84.

[30] For discussion, see: R Baldwin, 'Is Better Regulation Smarter Regulation?' (2005) Public Law 485; R Devon, 'Towards a Social Ethics of Technology: A Research Prospect' (2004) 8 Techne 99; S Jasanoff, 'Technologies of Humility: Citizen Participation in Governing Science' (2003) 41 Minerva 223; H Nowotny, 'How Many Policy Rooms Are There?' (2007) 32 Science, Technology & Human Values 479.

[31] Brownsword, above, n 5, 128. Further discussion at 120–128 includes: D Galligan, 'Citizens' Rights and Participation in the Regulation of Biotechnology' in F Francioni (ed), *Biotechnologies and International Human Rights* (Hart Publishing, Oxford 2007).

[32] R Brownsword, 'Human Dignity, Ethical Pluralism, and the Regulation of Modern Biotechnologies' in T Murphy (ed), *New Technologies and Human Rights* (Oxford University Press, Oxford 2009).

the legitimation of the regulatory process[33] and its outcome, i.e. helping foster confidence in and the consumption of innovation.[34]

Resonant here is work from critical theory, especially that influenced by Foucault. A major insight is the importance of power/knowledge. Knowledge is formulated as encompassing 'the vast assemblage of persons, theories, projects, experiments and techniques that has become such a central component of government'—it is 'the "know how" that makes government possible'.[35] In its relation to power, knowledge helps to provide the basis for regulation. This, in turn, is fused with and ordered by a neoliberal political rationality, which seeks to make the subjects of regulation 'complicit' with it.[36] In this light, citizen participation in nanoregulation for medical application looks like yet another means of producing docile subjects who actively regulate themselves.[37]

It is clear that regulation embeds a range of societal concerns, organizational aims, and individual aspirations (as both socio-legal scholars and regulators themselves are of course well aware). However, the target of regulation—science and technology—can itself be understood in these terms, as STS has long shown. This discipline emphasises the importance of investigating the construction, use, and deployment of scientific facts,[38] including how knowledge

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[33] J Black, 'The Emergence of Risk-Based Regulation and the New Public Risk Management in the United Kingdom' (2005) Public Law 512; J Black, 'Tensions in the Regulatory State' (2007) Public Law 58.

[34] Cf G Bache, ML Flear, and TK Hervey, 'The Defining Features of the European Union's Approach to Regulating New Health Technologies' in ML Flear, A-M Farrell, TK Hervey, and T Murphy (eds), *European Law and New Health Technologies* (Oxford University Press, Oxford 2013 (Forthcoming)).

[35] N Rose and P Miller, 'Political Power Beyond the State: Problematics of Government' (1992) 43 (2) British Journal of Sociology 172, 178.

[36] M Foucault, *The History of Sexuality: Volume One, The Will to Knowledge* (Penguin, London 1998); M Foucault, *Security, Territory, Population: Lectures at the Collège de France, 1977–1978* (Palgrave Macmillan, Basingstoke 2007); M Foucault, *The Birth of Biopolitics: Lectures at the Collège de France, 1978–1979* (Palgrave Macmillan, Basingstoke 2008). Cf T Lemke, ''The Birth of Biopolitics': Michel Foucault's Lecture at the Collège de France on Neo-liberal Governmentality' (2001) 30 (2) Economy and Society 190; W Brown, *Edgework* (Princeton UP, Woodstock 2005), 39–44.

[37] D Lupton, *Medicine as Culture: Illness, Disease and the Body in Western Society* (Sage, London 1994); BS Turner, *Medical Power and Social Knowledge* (2nd edn Sage, London 1995).

[38] K Knorr Cetina, 'Laboratory Studies: The Cultural Approach to the Study of Science' in S Jasanoff and others (eds), *Handbook of Science and Technology Studies* (Sage, London 1995); B Latour, *Science in Action. How to Follow Scientists and Engineers through Society* (Harvard University Press, Cambridge, MA 1987); M Lynch and S Woolgar (eds), *Representation in Scientific Practice* (MIT Press, Cambridge, MA 1990); A Pickering (ed), *Science as Practice and Culture* (University of Chicago Press, Chicago 1992).

is 'incorporated into practices of state-making, or of governance more broadly'.[39] For STS scholars, what we know, how we know it, and what we do are always co-produced.

As with knowledge, so too its material embodiments; sociological and STS research has long shown how technology has a social life of its own. Society is 'built into' artefacts, through ideas concerning how they might and should be used, and how they are eventually implemented.[40] In some cases, prospective users are literally included in the design process; in other cases, they are included as imaginaries which reflect innovators' own social location.[41] At the same time, the material world (including technoscientific innovation) impacts powerfully on our experience of our selves and one another; it is constitutive of subjectivity and social life.[42] Technologies, then, especially those concerned with health, are 'political machines'[43] which become embroiled with and further engender biopolitical debates and campaigns.[44]

STS research on the ways in which users are configured (or not) by technologies is also germane to recent work within regulatory studies.[45] Within this latter literature, analysts are asking hard questions about the accountability of technologies which prescribe user behaviour—and hence shape, constrain, or perhaps even eliminate human agency.[46] Work on 'design-based regulation' is (like STS) concerned with what norms, values, virtues, and behavioural options are 'designed-in' and 'designed-out' of technologies, and how these can

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[39] S Jasanoff, 'The Idiom of Co-production' in S Jasanoff (ed), *States of Knowledge* (Routledge, London 2004) 3.

[40] L Winner, 'Do Artefacts Have Politics?' (1980) 109 Daedalus 121–136; D MacKenzie and J Wajcman (eds), *The Social Shaping of Technology, Second Edition* (Open University Press, Buckingham 1999).

[41] L Neven, '"But Obviously It's Not for Me": Robots, Laboratories and the Defiant Identity of Elder Test Esers' (2010) 32 Sociology of Health & Illness 335; M Pickersgill, 'Standardising Antisocial Personality Disorder: The Social Shaping of a Psychiatric Technology' (2012) 34 Sociology of Health & Illness 544; G Walker and others, 'Renewable Energy and Sociotechnical Change: Imagined Subjectivities of "The Public" and Their Implications' (2010) 42 Environment and Planning A 931.

[42] T Dant, *Materiality and Society* (Open University Press, Maidenhead 2005).

[43] Cf A Barry, *Political Machines: Governing a Technological Society* (Athlone Press, London 2001).

[44] N Rose, *The Politics of Life Itself: Biomedicine, Power and Subjectivity in the 21st Century* (Princeton UP, Oxford 2007).

[45] M Akrich, 'The De-scription of Technical Objects' in WE Bijker and J Law (eds), *Shaping Technology/Building Society: Studies in Sociotechnical Change* (MIT Press, Cambridge, MA 1992); N Oudshoorn and T Pinch (eds), *How Users Matter: The Co-Construction of Users and Technologies, New Edition* (MIT Press, Cambridge, MA 2005); S Woolgar, 'Configuring the User: The Case of Usability Trials' in J Law (ed), *A Sociology of Monsters: Essays on Power, Technology and Domination* (Routledge, London 1991).

[46] Lessig, above, n 18.

and commonly do inhibit or prevent action.[47] Issues pertaining to oversight and legitimacy, and the place of public participation in innovation, are brought to the fore by Yeung and Dixon-Woods in their examination of design-based regulation and patient safety: 'when rules are embedded in the fabric of design, there is no legal or constitutional obligation on those who identify and design-in the rules to invite participation from *those likely to be affected*, let along take into account other *stakeholder interests*'.[48] This may 'obscure normative and programmatic commitments on the part of the designers, allow penetration of commercial and other interests, *reduce professional and public accountability*, [. . .] and *transfer judgments on the tolerability of risk to unaccountable institutions for which there is little transparency or public accountability*'.[49]

These comments loop back into STS concerns with participation, which—as a consequence of its centrality within innovation policy and practice—has received considerable attention. Many working within STS view participation as a (potential) means of democratising science and technology, helping to ensure responsible and responsive innovation.[50] For instance, participation has been figured as a 'technology of humility' that can be used to identify the normative in the technical and as such supplement the dominant 'technologies of hubris' of risk regulation.[51] These are complex systems and means of producing stability and economic optimisation, presented as apolitical with the effect of concealing their construction and limitations (such as regulatory distortions and failures).

At the same time, STS has been enduringly critical of forms of participation that seek not to include public perspectives, but rather to induce trust in science and produce acquiescence. Questions are continuously asked regarding *who* shapes the design of participation, *why* this is,

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[47] Brownsword, above, n 17; K Yeung, 'Towards an Understanding of Regulation by Design' in R Brownsword and K Yeung (eds), *Regulating Technologies: Legal Futures, Regulatory Frames and Technological Fixes* (Hart Publishing, Oxford 2008).

[48] K Yeung and M Dixon-Woods, 'Design-based Regulation and Patient Safety: A Regulatory Studies Perspective' (2010) 71 (3) Social Science & Medicine 613, 617. Emphasis added.

[49] Ibid. Emphasis added.

[50] K Bickerstaff and others, 'Locating Scientific Citizenship: The Institutional Contexts and Cultures of Public Engagement' (2010) 35 (4) Science, Technology & Human Values 474; S Cunningham-Burley, 'Public Knowledge and Public Trust' (2006) 9 Community Genetics 204; R Evans and A Plows, 'Listening Without Prejudice? Re-discovering the Value of the Disinterested Citizen' (2007) 37 (6) Social Studies of Science 827; M Pickersgill, 'Research, Engagement and Public Bioethics: Promoting Socially Robust Science' (2011) 37 Journal of Medical Ethics 698; T Togers-Hayden, A Mohr, and N Pidgeon, 'Introduction: Engaging with Nanotechnologies—Engaging Differently?' (2007) 1 (2) NanoEthics 123.

[51] Jasanoff, above, n 30.

how it is achieved, and to *what* ends. Such interrogation is propelled by the longstanding concern of STS scholars with policies and practices that figure citizens as ignorant and in need of education. These pluralised and grew in prominence during the 1990s along with widely felt unease regarding advances in (and the potential applications of) genetic engineering/modification. Many influential actors regarded this lack of trust in science as a deficit in knowledge, and various activities were convened in a range of countries in order to address this through education. Such endeavours neglected, however, the fact that individuals know about diverse things in different ways, have a range of expertise, and are often reflexively aware of limitations to their comprehension of particular sociotechnical developments and may actively seek to address these.[52] A number of scientists and policy makers have responded to these critiques from STS, and today exercises that were once aimed at increasing the public *understanding of* science are now more frequently viewed as opportunities to promote public *engagement with* science (implying a more 'two-way' dialogue). STS scholars have also come to be increasingly reflective about the ways in which they themselves may contribute to the more problematic aspects of public participation they have traditionally outlined, as they are now enrolled as key actors in the deployment of such participatory technologies.[53]

Recent STS work on the sociology of expectations and the power of promissory discourse (e.g. statements and debates about the future promise of technologies which do not yet exist) also connects to critiques of (particular modes) of citizen participation.[54] Within this

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[52] A Irwin and M Michael, *Science, Social Theory and Public Knowledge* (Open University Press, Maidenhead 2003); A Kerr, S Cunningham-Burley, and A Amos, 'The New Genetics and Health: Mobilizing Lay Expertise' (1998) 7 (1) Public Understanding of Science 41; BE Wynne, 'Knowledges in Context' (1991) 16 Science, Technology & Human Values 111; BE Wynne, 'Misunderstood Misunderstandings: Social Identities and Public Uptake of Science' (1992) 1 Public Understanding of Science 281.

[53] P-B Joly and A Kaufman, 'Lost in Translation? The Need for "Upstream Engagement" with Nanotechnology on Trial' (2008) 17 (3) Science as Culture 225; BE Wynne, 'Dazzled by the Mirage of Influence? STS-SSK in Multivalent Registers of Relevance' (2007) 32 (4) Science, Technology & Human Values 491.

[54] M Fortun, *Promising Genomics: Iceland and deCODE Genetics in a World of Speculation* (University of California Press, Berkeley 2008); A Hedgecoe and P Martin, 'The Drugs Don't Work: Expectations and the Shaping of Pharmacogenetics' (2003) 33 Social Studies of Science 327; M Pickersgill, 'Connecting Neuroscience and Law: Anticipatory Discourse and the Role of Sociotechnical Imaginaries' (2011) 30 (1) New Genetics and Society 27; M Pickersgill, '"Promising" Therapies: Neuroscience, Clinical Practice, and the Treatment of Psychopathy' (2011) 33 Sociology of Health & Illness 448; S Shapin, *The Scientific Life: A Moral History of a Late Modern Vocation* (University of Chicago Press, Chicago 2008); K Sunder Rajan, *Biocapital: The Constitution of Post-Genomic Life* (Duke University Press, London

literature, ideas about the future have been shown to be 'resources' that can be mobilised by credible individuals and organisations in order to lend further legitimacy to current research practices. Promissory or anticipatory discourses can be regarded as, in a sense, able to 'bring the future into the present'; in so doing, it is rendered as a commodity that can be acted upon in order to literally produce the realities future-orientated discourse describes while constraining or even eliminating the conditions of possibility for others. This may involve the galvanisation of bioethical scholarship to tease out the implications of (prospective) science for society, and hence to provide a kind of regulatory roadmap for innovators to follow in order to expedite the realisation of the futures they have worked so hard to imagine.[55] Public participation is a key site where debate around futures is played out, and the kinds of futures made discursively available to citizens engaging in participatory techniques is thus salient since these can, literally, be talked into existence.

Thus far, we have drawn on a range of literature from law, regulatory studies, critical theory, and STS in order to outline some of the political and regulatory logics underpinning and animating public participation in science and technology, and sketched out some of the associated critiques and concerns that have been advanced in regards to participatory techniques. In what follows, we go on to consider how the EU currently fosters and regulates innovation and relates this regime to public participation, before, in turn, examining how that conceptual and normative backdrop is further refined in the broad structures of nanoregulation, and how all of that underpins the design of participatory processes. In tracing the gradual hardening of the conditions of possibility for technologies of participation, we do not seek to propose a specific design for them. Rather, underpinned by a concern for democratic decision-making, we aim to foster a vantage point that seeks to promote discussion on an important yet overlooked aspect of their design: critical reflection on the regulation of publics and the limits on their regulatory potential.

2006); E Thacker, *The Global Genome: Biotechnology, Politics and Culture* (MIT Press, Cambridge, MA 2005); C Thompson, *Making Parents: The Ontological Choreography of Reproductive Technologies* (MIT Press, Cambridge, MA 2005); C Selin, 'Expectations and the Emergence of Nanotechnology' (2007) 32 Science, Technology & Human Values 196; C Selin, 'The Sociology of the Future: Tracing Stories of Technology and Time' (2008) 2 Sociology Compass 1878; N Brown, B Rappert, and A Webster (eds), *Contested Futures: A Sociology of Prospective Technoscience* (Ashgate, Aldershot 2000).

[55] Hedgecoe and Martin, ibid.

III. INNOVATION AND PARTICIPATION IN THE EU

A. Programmatic Level

In the context of the EU, (nano)regulation fits within, and is underpinned at the programmatic level, the overarching steer for EU governance, by the 2000 European Council Lisbon Strategy.[56] Here research was presented as 'the *driver* for the *production and exploitation of knowledge* [making it] above all a *linchpin* in the implementation of the Lisbon strategy to make Europe the *most* dynamic and competitive, *knowledge-based economy* in the world, capable of sustaining economic growth, employment and social cohesion'.[57] EU funding of research and development was, and continues to be, seen as integral to the creation of a European Research Area, which aims to 'reinvigorate research in Europe',[58] and is linked to the Lisbon Strategy as part the so-called knowledge triangle of research, education, and innovation.[59] Importantly, while EU funding is limited by the principle of 'European added value',[60] it is directed at enabling discourse between researchers in different Member States (MSs) in order to foster the economic competitiveness of European industry,[61] and integration.[62]

The Lisbon Strategy was subsequently refocused on growth and jobs,[63] and in 2010 this was intensified in light of the recent European financial crisis in the European Commission (Commission) 'Europe 2020' strategy

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[56] Council of the European Union, *Presidency Conclusions—Lisbon European Council, 23rd and 24th March* (Brussels 2000). See: K Armstrong, 'Governance and Constitutionalism After Lisbon' in *JCMS Symposium: EU Governance After Lisbon* (2008) 46 Journal of Common Market Studies 413.

[57] European Commission, *Building the ERA of Knowledge for Growth*, COM(2005) 118 final, 2. Emphasis added.

[58] European Commission, *Towards a European Research Area*, COM(2000) 6 final, 5.

[59] European Commission, *Innovation Tomorrow Innovation Policy and the Regulatory Framework: Making Innovation an Integral Part of the Broader Structural Agenda*, Prepared by Louis Lengrand and Associés, PREST (University of Manchester) and ANRT (France). Innovation papers No. 28. Directorate-General for Enterprise (Office for Official Publications of the European Communities, Luxembourg 2002); European Commission, *Putting Knowledge into Practice: A Broad-based Innovation Strategy for the EU*, COM(2006) 502 final.

[60] Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007–2013) OJ 2006 L 412/1.

[61] TK Hervey and JV McHale, *Health Law and the European Union* (Cambridge University Press, Cambridge 2004), 243–244.

[62] R Gusma'o, 'Research Networks as a Means of European Integration' (2003) 23 Technology in Science 386.

[63] W Kok, *Facing the Challenge: The Lisbon Strategy for Growth and Employment. Report from the High Level Group Chaired by Wim Kok* (European Commission, Brussels 2004).

for economic growth.[64] The focus on optimising the economy by and through the exploitation of knowledge (such as that produced by nanoresearch)[65]and the propagation of 'knowledge workers' is also evident in the nanotechnology policy domain, where it is linked to EU funding of innovation through its Framework Programmes (FP). For instance, in the seventh FP, FP7,[66] even basic research—including on nanotechnology[67]—is framed as a driver of growth and understood as signifying a forward march of progress,[68] rather than being regarded as a means of increasing knowledge and understanding as an end in itself.[69]

As such, (nano)science and (nano)technology are embedded within a network that constructs the EU's identity, and its narrative about itself (including in terms of what it regulates, how, and why). As we will see, these both seek to reflect and produce public perceptions of nanotechnologies; such perceptions themselves help to sanction—and thus play a role in producing—particular futures where in nanoscience and technology plays a key role.[70] In particular, there is an effort to privilege and support the creation and production of innovative nanoproducts in order to enhance the internal market,[71] and ultimately the wider project of European integration.

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[64] See, generally: <http://ec.europa.eu/europe2020/index_en.htm> last accessed 14 March 2012. Also see: European Commission, *Smart Regulation in the European Union*, COM (2010) 543 final; European Commission, *Europe 2020 Flagship Initiative Innovation Union*, COM (2010) 546 final.

[65] 'Commission launches consultation on EU 2020: a new strategy to make the EU a smarter, greener social market': <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/09/1807>.

[66] Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for Research, Technological Development and Demonstration Activities (2007–2013) OJ 2006 L 412/1.

[67] Nanotechnologies are highlighted in the FP7 objectives, in such references as 'the development and validation of new therapies[. . .]diagnostic tools and medical technologies'. The activities to be funded include '[i]nnovative therapeutic approaches and intervention' ie '[t]o research, consolidate and ensure further developments in advanced therapies and technologies with potential application in many diseases and disorders such as new therapeutic tools for regenerative medicine'. Importantly, much of the focus of FP7 is on 'translational research' which attempts to translate basic research into usable (or marketable) technologies. See: *Proposed Priorities for Innovative Health Research 2012* (http://ec.europa.eu/research/health/pdf/fp7-health-2012-orientation-paper_en.pdf (last accessed 1 May 2012)).

[68] Cf SHE Harmon, 'Motivating Values and Regulating Models for Emerging Technologies: Stem Cell Research Regulation in Argentina and the United Kingdom' in M Freeman (ed), *Law and Ethics* (Oxford University Press, Oxford 2008), 147.

[69] Bache and others, above, n 34.

[70] C Tourney, 'Narratives for Nanotech: Anticipating Public Reactions to Nanotechnology' (2004) 8 Techne 88.

[71] 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'. The establishment of the internal market is required by Art 3(3) amended TEU.

B. Nanoregulation

The overarching concerns found at the programmatic level are reflected in discourse on (and constitutive of) nanotechnology.[72] For instance, in *Towards a European Strategy for Nanotechnology* (Nanotechnology Strategy), the Commission states:

> [in] today's globalised market, long-term economic success is increasingly dependent on the generation, management and exploitation of knowledge. Investment in R&D is needed to produce knowledge and industrial innovation, [which] in turn, needs knowledge to produce wealth. In this way, the loop is closed and fresh private capital can be injected into R&D.[73]

Unlocking 'the potential of this knowledge' is also part of the constitution of the EU's identity in relation to the rest of the world, as it seeks to project power and generate legitimacy through competitive industries and the cultivation of 'new European *knowledge-based* industries'.[74]

Ultimately, European 'excellence in nanosciences must finally be translated into *commercially viable products and processes*'. Nanotechnology is presented as being 'one of the most *promising* and rapidly *expanding* fields of R&D to provide *new impetus towards the dynamic knowledge-based objectives of the Lisbon process*'.[75] The focus of EU efforts is then to '*ensure the creation and exploitation of the knowledge generated via R&D for the benefit of society*' through a range of actions which include increasing investment in and coordination of research and development, the construction of supporting infrastructure, and the advancement of interdisciplinary education that might result in researchers with, predictably, 'a stronger *entrepreneurial* mindset', and who will work within a socio-technical ecosystem that will provide 'favourable conditions for technology transfer and innovation' in order to 'ensure that European R&D excellence is *translated* into *wealth-generating products and processes*'.[76]

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[72] Council of the European Union, *Conclusions on Guidance on Future Priorities for European Research and Research-based Innovation*, 2982nd Competitiveness (Internal market, Industry, and Research) Council Meeting, Brussels, 3 December 2009. Available at: <http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/intm/111723.pdf> last accessed 1 March 2012.

[73] European Commission, above, n 11, 16.

[74] Ibid.

[75] Ibid. 3. Emphasis added.

[76] Ibid. Emphasis added.

Notably, and as elaborated below, these rationales are endorsed by the EU's harnessing of bioethics. In its *Opinion on the Ethical Aspects of Nanomedicine* (Opinion), the European Group on Ethics in Science and New Technologies (EGE) justifies EU funding and investment into research and development, and, as we shall see, seeks to develop nanoregulation through the leveraging of risk and scientific uncertainty.[77] As Harvey and Salter point out, novel science 'gives bioethical expertise access to new governance territory; *bioethical expertise gives sciences access to political acceptability*'.[78] Accordingly, we should not be surprised that the EGE has endorsed risk-orientated regulation that seeks to foster and direct, rather than circumscribe, innovation in nanotechnology. Indeed, for biotechnologies in general, the EGE has been shown to be an important means of providing legitimacy and garnering support for innovation.[79]

The EGE's Opinion is supplemented by the 2007 *Code of Conduct for Responsible Nanosciences and Nanotechnologies Research Consultation Paper* (CoC Consultation Paper)[80] and 2008 *Code of Conduct for Responsible Nanosciences and Nanotechnologies Research* (Code of Conduct).[81] In the CoC Consultation Paper, the Commission states that the resultant code should be 'a basis for international dialogue in this area, where Europe has taken a proactive role'.[82] Standard legal foundations[83] were combined with principles, norms, and values

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[77] EGE, above, n 11.

[78] A Harvey and B Salter, 'Anticipatory Governance: Bioethical Expertise for Human/Animal Chimeras' (2012) Science as Culture 1. Emphasis added.

[79] H Busby, T Hervey, and A Mohr, 'Ethical EU law? The Influence of the European Group on Ethics in Science and New Technologies' (2008) 33 European Law Review 803.

[80] European Commission, *Towards a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research, Consultation Paper*, 2007 (available at: <http://ec.europa.eu/research/consultations/pdf/nano-consultation_en.pdf> last accessed 8 March 2012), 3.

[81] European Commission, *Code of Conduct for Responsible Nanosciences and Nanotechnologies Research*, C(2008) 424 final.

[82] European Commission, above, n 80, 2.

[83] Charter of Fundamental Rights of the European Union (2000) (with the implementation of the Treaty of Lisbon on 1 December 2009, Art 6 amended Treaty on European Union (TEU) gives this the same status as the Treaties) and the general principles resulting from relevant international treaties such as the European Convention on Human Rights (1950) (noted as a source for the general principles of EU law in Art 6(3) amended TEU, with the EU's accession to the Council of Europe being required under Art 6(2) amended TEU), and 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 (the Oviedo Convention) (1997), and the Convention on Access to Information, Public Participation in Decision-Making, and Access to Justice in Environmental Matters (the Aarhus Convention) (1998). See: European Commission, above, n 80, 2.

found in policy documents, including the Nanotechnology Strategy and the EGE's Opinion,[84] which together are taken to be 'core European values, such as integrity, autonomy, privacy, equity, fairness, pluralism and solidarity'.[85] Three key principles of 'precaution, inclusiveness, and integrity'[86] were highlighted as necessary to structure the Code of Conduct, with the aim of ensuring that nano-innovation contributes to 'improving human well-being' while also guarding against 'possible threats to human well-being'.[87] These points were largely duplicated, albeit in a slightly reconfigured and simplified form in the Code of Conduct as 'general principles' (some of which are highlighted in the next section): meaning (explained as 'comprehensible to the public' and respectful of 'fundamental rights and be conducted in the interest of the well-being of individuals and society'[88]), sustainability, precaution, inclusiveness, excellence, innovation, and accountability.[89]

The Code of Conduct is an important technology through which the EU produces its identity: specifically, it presents EU innovation as rational and legitimate, while also rendering it more governable (since a deviation from the code comes with an implicit or explicit threat of sanction).[90] The Code of Conduct is also a means by which the EU produces and exercises power—and, indeed, further contributes to the fostering of innovation, since 'the very process of deliberating about codes' help to 'build shared agendas' and enable 'future co-ordinated initiatives'.[91] At the same time, the kinds of bioethical discourses constitutive of codes of conduct are 'capable of legitimizing the regulatory polices necessary for maintaining public trust'.[92] Together, the CoC Consultation Paper and Code of Conduct underscore our points that regulation in the EU is designed to foster research, development and economic optimisation, orientated around risk, and animated through expectations about positive sociotechnical futures enabled by innovative science and technology. Overall, this is a means of presenting the EU as a legitimate,

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[84] Both referencing: European Commission, *The Precautionary Principle*, COM(2000) 1.
[85] European Commission, above, n 80, 3.
[86] Ibid.
[87] Ibid.
[88] European Commission, above, n 81, 6.
[89] Ibid 6–7.
[90] Cf A Abbot, 'Professional Ethics' (1983) 88(5) American Journal of Sociology 855.
[91] B Rappert, 'Pacing Science and Technology with Codes of Conduct: Rethinking What Works' in GE Marchant, BR Allenby, and JR Herkert (eds), *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight: The Pacing Problem* (Springer, Dordrecht 2011), 110.
[92] B Salter and C Salter, 'Bioethics and the Global Moral Economy: The Cultural Politics of Human Embryonic Stem Cell Science' (2007) 32 (5) Science, Technology & Human Values 554.

accountable body that is an international leader in socially robust innovation. Yet, as we go on to explain this attempt at producing legitimacy is undermined by the design of publics in nanoregulation.

C. Participation in Science and Technology

While the importance of ensuring the 'creation and exploitation of the knowledge generated via R&D for the *benefit of society*'[93] is noted by the Commission, those benefits are largely undefined. Given the predominant focus of the EU on economic optimisation, it is plausible that societal benefit is seen largely to emerge from this (if it is not directly reduced to it). Participation is tacked onto these actions through rather imprecise language that highlights the need to 'integrate *societal considerations* into the R&D process at an *early stage*'.[94] However, exactly why this should be is commonly unspecified. Furthermore, if participation may be deemed to have the potential to decelerate innovation, it would—under the normative regime the EU has built for itself—be more sensible to minimise the scope and impact of participatory techniques. It is with this in mind that social scientists noted in *Taking European Knowledge Society Seriously* that any 'loss of potential economic competitiveness is invoked as almost a 'state of emergency', such that efficiency overrides the slower and more cumbersome application of democratic principles'.[95]

The EU, then, has not formally institutionalised participation in or around the assemblage of actors and organisations regulating and constituting techno- and especially nano-science in Europe. While a range of initiatives such as citizen panels exist, the EU's more general weak legal commitment to participation is mirrored in its approach to nanoregulation and innovation. The weak legal foundations are found in, for example, the EU's Treaties[96] and, importantly in the nanotechnology sphere, one of the standard legal foundations for the Code of Conduct 'general principles' noted above, the Aarhus Convention (1998).

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[93] European Commission, above, n 11, 3. Emphasis added.
[94] Ibid. Emphasis added.
[95] *Taking European Knowledge Society Seriously: Report of the Expert Group on Science and Governance* (Office for Official Publications of the European Communities, Luxembourg 2007), 52.
[96] For instance, Art 2 TEU (the EU is 'founded on the values of respect for human dignity, freedom, *democracy*, equality, the rule of law and respect for *human rights*' (emphasis added)), Art 10(3) TEU ('[e]very citizen shall have the *right to participate* in the democratic life of the Union. Decisions shall be taken as openly and as closely as possible to the citizen' (emphasis added)), and Art 11(1) TEU ('[t]he institutions *shall*, by *appropriate* means, give *citizens and representative associations* the *opportunity* to *make known* and *publicly exchange* their views in *all areas of Union action*' (emphasis added)). See further: ML Flear and A Vakulenko, 'A Human Rights Perspective on Citizen Participation in the EU's Governance of New Technologies' (2010) 10 (4) Human Rights Law Review 661.

Although potentially important for the general field, this instrument focuses on supporting participation to address just environmental impacts and as such seems rather limited in relation to medical applications as it fails to address the full range of concerns they might raise.[97] Unsurprisingly then, participation is constructed more through (legally) non-binding policy statements.[98] These include *European Governance*,[99] which called for openness, transparency and enhanced public participation throughout the process of science-based decision making,[100] in order to reinforce accountability, and engender (or restore) public trust and legitimacy. This is especially orientated towards areas of risk and scientific uncertainty, such as nanotechnologies. Yet, even as participation has an underspecified regulatory role, the focus on innovation and the installation of a neoliberal orientation in EU regulation limits and implicitly steers the use of participation towards promoting rather than challenging or shaping scientific and technological research trajectories.[101]

Another key document, *Science and Society Action Plan*,[102] contains similar themes to those apparent within *European Governance* and other documents.[103] Supported by Public Understanding of Science

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[97] See above, n 83. For discussion, see: J D'Silva and G van Calster, 'For Me to Know and You to Find Out? Participatory Mechanisms, The Aarhus Convention and New Technologies' (2010) 4 (2) Studies in Ethics, Law, and Technology Art 3. See further: <http://ec.europa.eu/environment/aarhus/index.htm>.

[98] For discussion, see: *Taking European Knowledge Society Seriously*, above, n 95, 52.

[99] European Commission, *European Governance: A White Paper*, COM(2001) 428 final. For commentary, see: K Armstrong, 'Rediscovering Civil Society: The European Union and the White Paper on Governance' (2002) 8 European Law Journal 102. For an overview of initiatives, see: European Commission, *Commission Staff Working Document, Report on European Governance (2003–2004)*, SEC(2004) 1153. In the health sphere, one focus of new technologies, see European Commission, *White Paper, Together for Health: A Strategic Approach for the EU 2008–2013*, COM(2007) 630 final; European Commission, *Commission Staff Working Document Accompanying White Paper, Together for Health: A Strategic Approach for the EU 2008–2013*, SEC(2007) 1376.

[100] European Commission, *European Governance*, ibid, 8.

[101] Flear and Vakulenko, above, n 96.

[102] European Commission, *Science and Society Action Plan*, COM(2001) 714. See also: European Commission, *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.

[103] 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.

(PUS) techniques that actively seek to measure public opinion and knowledge, such as the Eurobarometer,[104] the focus is on the promotion of scientific education and culture, public awareness, science education, and the development of responsible polices that win wider confidence; for instance, through 'a structured dialogue' between scientists, industry, and civil society and the establishment of a Commission-led Stakeholders' Forum. Yet, at the same time, public involvement continues to be figured in terms of a 'deficit model' within which participation is a means of (much needed) education for citizens who are seen as deficient in their knowledge about science.[105] Such education may also more widely involve various other actors and institutions, such as media, researchers, universities, and industry. Overall, in general technologies of participation in the EU have tended to be used more to legitimate regulation, than ensure the (substantive) involvement of citizens in regulatory and priority setting in innovation.[106]

Having considered the general conceptual and normative backdrop for EU nanoregulation and its relationship to participation, in the next section we proceed to highlight the norms, values, and sociotechnical imaginaries immanent to the discourses. In doing so we ask whether the publics constructed are regulatory or regulated. We work in broad brush strokes rather than close detail in order to highlight examples that are indicative of the broader picture, focusing in particular on documents making forward-looking statements (especially the Nanotechnology Strategy[107]) and those considering codes of conduct.[108]

IV. THE PUBLIC IN EU NANOREGULATION

A. Anticipating (Certain) Nano-futures

It is, we believe, fair to say that expectations about the future are of paramount importance when considering the approach of the EU

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[104] European Commission, *Europeans, Science and Technology*, Special Eurobarometer 154, December 2001; European Commission, *Social Values, Science and Technology*, Special Eurobarometer 225, June 2005 <http://ec.europa.eu/public_opinion/archives/ebs/ebs_225_report_en.pdf> last accessed 2 May 2012.

[105] Flear and Vakulenko, above, n 96.

[106] Ibid.

[107] European Commission, above, n 11; see also: European Commission, *Nanosciences and Nanotechnologies: an Action Plan for Europe 2005–2009*, COM(2005) 243; European Commission, *Nanosciences and Nanotechnologies: An Action Plan for Europe 2005–2009. First Implementation Report 2005–2007*, COM(2007) 505 final; European Commission, *Nanosciences and Nanotechnologies: An Action Plan for Europe 2005–2009. Second Implementation Report 2007–2009*, COM(2009)607 final.

[108] Mainly available at <http://ec.europa.eu/health/nanotechnology/policy/index_en.htm>.

towards nanotechnology, including its medical applications. Indeed, in the Nanotechnology Strategy, nanotechnology is noted as '" horizontal", " key" or "enabling" since it can pervade virtually all technological sectors...and is *expected to lead to innovations that can contribute towards addressing many of the problems facing today's society*'.[109] Medical applications, noted earlier, are also regarded by the EU as one promising problem area, and are seen as including:

> miniaturised diagnostics that *could be* implanted for *early diagnosis* of illness. Nanotechnology-based coatings *can improve* the bioactivity and biocompatibility of implants. Self-organising scaffolds *pave the way* for new generations of tissue engineering and biomimetic materials, with the *long-term potential* of synthesising organ replacements. Novel systems for targeted drug delivery are *under development* and recently nanoparticles *could be* channelled into tumour cells in order to *treat* them, e.g. through heating.[110]

In light of such expectations, the integration of 'societal considerations into the R&D process at an *early stage*'[111] is one action for policy. As such, apparently in an effort to convince scientific experts and regulators, it is 'in the common interest to *adopt a proactive stance* and *fully integrate societal considerations* into the R&D process, *exploring its benefits, risks and deeper implications for society*'. Regulatory publics are seemingly encouraged—especially since this process 'needs to be carried out *as early as possible*'.[112] This is echoed by the EGE, which configures participation in relation to risk as 'societal dialogue' and notes the need for participation 'public concerns are approached and discussed *from the beginning*'.[113] Moreover, in the Code of Conduct, the general principle of 'inclusiveness' means that 'research activities should be guided by the principles of *openness to all stakeholders*, transparency and respect for the legitimate right of access to information. It should allow the *participation in decision-making processes* of all stakeholders involved in or concerned'.[114]

However, 'the complex and invisible nature of nanotechnology presents a *challenge for science and risk communicators*'.[115] In other words, as elaborated below, publics need to be educated if they are to be enrolled in regulation. This is to be achieved, in part, by 'governing

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[109] European Commission, above, n 11, 4. Emphasis added.
[110] Ibid. Emphasis added.
[111] European Commission, above, n 11, 3. Emphasis added.
[112] European Commission, above, n 11, 19. Emphasis added.
[113] EGE, above, n 11, para 4.4.4.2. Emphasis added.
[114] European Commission, above, n 81, 6. Emphasis added.
[115] European Commission, above, n 11, 19. Emphasis added.

anticipation', which indicates participation is a technology for the regulation of public expectations even as hopes and benefits are articulated:

> Without a serious communication effort, nanotechnology innovations could face an unjust negative public reception. An effective two-way dialogue is indispensable, whereby the general publics' views are taken into account and may be seen to influence decisions concerning R&D policy. The public trust and acceptance of nanotechnology will be crucial for its long-term development and allow us to profit from its potential benefits. It is evident that the scientific community will have to improve its communication skills.[116]

Of course, this implies a role for regulatory publics through dialogue about nanotechnology development. As Borup and colleagues point out, expectations are 'first and foremost "constitutive" or "performative" in *attracting* the interest of necessary allies (various actors in innovation networks, investors, regulatory actors, *users* and so on)'.[117] Unsurprisingly then, the expectations associated with nanotechnology propel investment in this area, with public (and even private) funding endorsed by the EGE.[118] Perhaps, especially in regards to medical applications, there is also, as Doubleday notes, a concomitant expansion in social and ethical engagement and debate.[119] In particular, nanoregulation brings to the fore different and contested ideas of not just the technology to be brought into being and regulated, but also how it will fit into society, and how different notions of human dignity and morality will be defined, perpetuated, and perhaps reshaped.[120]

At the same time, however, visions of the medical and economic import of the technology regulate publics through defining what is 'at stake', and by implication the citizens included as stakeholders[121] in

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[116] Ibid, 20. Emphasis added.

[117] M Borup and others, 'The Sociology of Expectations in Science and Technology' (2006) 18 Technology Analysis and Strategic Management 285, 289. Emphasis added.

[118] EGE, above, n 11, paras 4.4.4.2 and 4.4.4.3, and Appendix 1.

[119] R Doubleday, 'Risk, Public Engagement and Reflexivity: Alternative Framings of the Public Dimensions of Nanotechnology' (2007) 9 (2) Health, Risk & Society 211; R Doubleday, 'Organizing Accountability: Co-production of Technoscientific and Social Worlds in a Nanoscience Laboratory' (2007) 39 (2) Area 166.

[120] Cf R Brownsword, 'What the World Needs Now: Techno-regulation, Humanity, Human Rights and Human Dignity' in R Brownsword (ed), *Global Governance and the Quest for Justice* (Hart Publishing, Oxford 2004).

[121] For the EU, stakeholders here are—in theory—extremely broad, included 'Member States, employers, research funders, researchers, and more generally all individuals and civil society organisations engaged, involved or interested in N&N [nanoscience and nanotechnology] research' (European

participatory techniques. For instance, the focus on hope, benefit, and similar expectations might support and privilege—or, in other words, design-in—the articulation of human rights and utilitarian-based ethics, respectively,[122] while limiting the discursive space for—and implying the design-out of—a dignitarian ethic. In any case, the limited discursive space undermines procedural epistemic integration of more pessimistic or, perhaps more accurately, contrary voices in participatory techniques. As a consequence, such voices might be constrained, or even squeezed out and silenced.[123] In short, the focus on hope and other positive expectations enrols, and prioritises the inclusion of and the voicing of claims by, those individuals and groups who actively campaign towards, for example, public funding or research that addresses their concerns and supports the development of nano-enabled 'hope technologies'.[124] Recognised in diverse studies from various disciplines, such individuals and groups include those whose biology or medical status[125] renders them particularly interested in innovation for the treatment of their conditions.[126]

In relation to 'accountability', the Code of Conduct states '[*r*]*esearchers and research organisations* should remain accountable for the social, environmental and human health impacts that their N&N [nanoscience and nanotechnology] research may impose on present and future

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Commission, above, n 81, 6). Yet, in practice, only certain citizens can be included in public participation.

122 M Horst, 'Public Expectations of Gene Therapy: Scientific Futures and Their Performative Effects on Scientific Citizenship' (2007) 32 Science, Technology & Human Values 150; C Novas, 'The Political Economy of Hope: Patients' Organizations, Science and Biovalue' (2006) 1 BioSocieties 289.

123 Cf B Anderson, 'Hope for Nanotechnology: Anticipatory Knowledge and the Governance of Affect' (2007) 39 (2) Area 156, 157. Emphasis added.

124 A term developed in relation to assisted reproductive therapies: S Franklin, *Embodied Progress: A Cultural Account of Assisted Conception* (Routledge, London 1997). For a more general discussion of new technologies, hope and law, see: M-A Jacob and B Prainsack, 'Embryonic Hopes: Controversy, Alliance, and Reproductive Entities in Law and the Social Sciences' (2010) 19 (4) Social & Legal Studies 497, a debate and dialogue, and especially: M Fox and T Murphy 'Can Law Facilitate Embryonic Hopes?'.

125 J Sawicki, *Disciplining Foucault: Feminism, Power, and the Body* (Routledge, New York 1991).

126 Such as: 'moral pioneers' in R Rapp, *Testing Women, Testing the Fetus: The Social Impact of Amniocentesis in America* (Routledge, London 2000); 'genetic citizens' in D Heath, R Rapp, and K-S Taussig, 'Genetic Citizenship' in D Night and J Vincent (eds), *A Companion to the Anthropology of Politics* (Blackwell, Oxford 2004); 'biological citizens' in N Rose and C Novas, 'Biological Citizenship' in A Ong and S Collier (eds), *Global Assemblages: Technology, Politics, and Ethics as Anthropological Problems* (Blackwell, Oxford 2005), Cf J Biehl, *Will to Live: AIDS Therapies and the Politics of Survival* (Princeton UP, Princeton 2007). Also see: A Panofsky, 'Generating Sociability to Drive Science: Patient Advocacy Organizations and Genetics Research' (2011) 41 Social Studies of Science 31.

generations'.[127] Moreover, Borup and colleagues note how promissory discourses are implicated 'in *defining roles* and in *building mutually binding obligations and agendas*'.[128] That is, participation as part of hopeful scientific citizenship is also a technique of responsibilisation (i.e. a means of making citizens feel responsible) that helps further regulate publics and mediate and limit EU accountability.[129] Even as some non-expert stakeholders' voices are privileged, they are implicated in taking (part of) the blame in the event of failure, if and when some hopes are dashed and some fears are realised.[130] This helps to limit and legitimate regulatory objectives and options, and maintain legitimacy in the event of failure.[131]

B. Engaging with Risk

Anticipation and expectation are central to, and indeed constitutive of, nanoscience and technology.[132] Yet, the risk profile of nanotechnology is likewise salient, and, as noted above, key to how it is regulated. Indeed, risk is central in the leveraging of uncertainty to support nanoregulation,[133] bringing nanotechnological futures into the present,[134] and further configuring the conditions of possibility for participation.[135]

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[127] European Commission, above, n 81, 6–7. Emphasis added.
[128] M Borup and others, 'The Sociology of Expectations in Science and Technology' (2006) 18 Technology Analysis and Strategic Management 285, 289. Emphasis added.
[129] Doubleday, above, n 119.
[130] D Barney, 'The Morning After: Citizen Engagement in Technological Society' (2006) 9 Techne 23; H Nowotny, 'Wish Fulfilment and its Discontents' (2003) 4 EMBO Reports 917; R Tutton, 'Promising Pessimism: Reading the Futures to be Avoided in Biotech' (2011) 41 (3) Social Studies in Science 411. Cf T Murphy, 'Technology, Tools and Toxic Expectations: Post-Publication Notes on *New Technologies and Human Rights*' (2009) 2 Law, Innovation and Technology 181.
[131] Horst, above, n 122; M Elam and M Bertilsson, 'Consuming, Engaging and Confronting Science: The Emerging Dimensions of Scientific Citizenship' (2007) 6 European Journal of Social Theory 233.
[132] Anderson, above, n 123.
[133] 'Risk assessment and dialogue at the EU level': <http://ec.europa.eu/health/dialogue_collaboration/system/index_en.htm>. On EU risk regulation in general see: L Fisher, *Risk Regulation and Administrative Constitutionalism* (Hart Publishing, Oxford 2007); V Heyvaert, 'Governing Climate Change. Towards a New Paradigm for Risk Regulation' (2011) 74 (6) Modern Law Review 817; M Lee, 'Beyond Safety? The Broadening Scope of Risk Regulation' in C O'Cinneide (ed), *Current Legal Problems 2009* (Oxford University Press, Oxford 2010).
[134] 'Assessing safety': <http://ec.europa.eu/health/nanotechnology/assessing_safety/index_en.htm>.
[135] 'Stakeholders and citizens': <http://ec.europa.eu/health/nanotechnology/citizens_view/index_en.htm>.

The 'awareness' of the 'general public' about nanotechnology is identified as growing, regarded as evidenced through requests for information and the raising of safety concerns.[136]

While much discourse around nanotechnology is promissory, this also includes negative expectations such as anxiety about sociotechnical change and fears about safety.[137] It is this, then, which provides a basis for public engagement in risk regulation. For instance, as is asserted in the CoC Consultation Paper:

> Good governance of nanosciences and nanotechnologies implies an open and transparent *public dialogue* addressing possible risks and realistic expectations. The Code of Conduct could *address the requirement of explicit consideration of the limits of knowledge and control over the development of the technology*. It could also highlight the *need to avoid economic risk* and *inappropriate public investments* in nanotechnology.[138]

Furthermore, as noted in the Nanotechnology Strategy:

> Some people criticise the scientific community for being too far removed from the mechanisms of democracy with a lack of public understanding, public perception of risks versus benefits, and *public participation and possibility of control*. While the potential applications of nanotechnology can improve our quality of life, there may be some risk associated with it, as with any new technology—this should be openly acknowledged and investigated. At the same time *the public's perception of nanotechnology and its risks should be properly assessed and addressed*.[139]

Accordingly, the Nanotechnology Strategy notes that nanotechnology 'must be *developed in a safe and responsible manner*. Ethical principles must be adhered to and potential health, safety or environmental risks scientifically studied, also in order to *prepare* for possible regulation'.[140]

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[136] Above, n 104: <http://ec.europa.eu/public_opinion/archives/ebs/ebs_225_report_en.pdf> last accessed 15 March 2012.

[137] J Balbus and others, 'Getting Nanotechnology Right the First Time' in G Hunt and M Mehta (eds), *Nanotechnology: Risk, Ethics and Law* (Earthscan, London 2006); R Clift, 'Risk Management and Regulation in an Emerging Technology' in G Hunt and M Mehta (eds), *Nanotechnology: Risk, Ethics and Law* (Earthscan, London 2006).

[138] European Commission, above, n 80, 4. Emphasis added.

[139] European Commission, above, n 11, 19. Emphasis added.

[140] Ibid, 3. Emphasis added.

Within this discursive arena, public engagement can be read as a means of risk communication,[141] resonant with the call to 'govern anticipation' noted above. The overriding focus on safety is reinforced by the EGE, which outlines other ethical questions pertaining to nanotechnology,[142] and asks: 'how do we check that, because of their greater capacity to pass through biological systems ... nanodevices designed for drug delivery would not induce negative side-effects for patients[?]'.[143] Overall, then, the focus is on a technical model of risk, including a narrow range of matters 'at risk', such as 'health and environmental risks'.[144] This ensures the privileging of expert interpretation of scientific data and their provision of 'risk knowledge', which regulates publics as it implicitly reduces—and designs-out—the importance of their (non-expert) participation. Revealingly, risk, instantiated as safety, is the prime concern for dialogue prefigured by 'information sharing',[145] and directed at 'success'.[146]

Precaution might provide additional space for participation and regulatory publics through explicit reference to societal concerns and norms.[147] As noted above, precaution is mentioned in (for example) the Code of Conduct as a key general principle, and again in the Nanotechnology Strategy: 'The Precautionary Principle, as used up to now, could be applied in the event that *realistic and serious risks are identified*'.[148] Similarly, the EGE notes 'uncertainties and knowledge gaps associated with new nanotechnology-based diagnostics, therapies and preventive measures should be identified. These uncertainties need to be characterized and measures have to be developed in order to reduce them as far as possible'.[149] However, in both of these examples, precaution is marginalised to risk management. In effect, there is, as Brownsword puts it, 'no risk to

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[141] N Pidgeon and T Rogers-Hayden, 'Opening Up Nanotechnology Dialogue with the Publics: Risk Communication of 'Upstream Engagement'?' (2007) 9 (2) Health, Risk & Society 191.

[142] Including those pertaining to human rights, justice and solidarity, the environment, and .... See: EGE, above, n 11, para 4.3.

[143] EGE, above, n 11, para 4.21, especially 38.

[144] European Commission, above, n 11, 21.

[145] 'Information sharing and dialogue': <http://ec.europa.eu/health/nanotechnology/citizens_view/index_en.htm>.

[146] 'Nano safety for success dialogue': <http://ec.europa.eu/health/nanotechnology/citizens_view/index_en.htm>; 'Past events': <http://ec.europa.eu/health/nanotechnology/events/index_en.htm>.

[147] In that 'the determination of a tolerable risk level generally requires the involvement of the public in one way or another' in L Boisson de Chazournes, 'New Technologies, the Precautionary Principle, and Public Participation' in T Murphy (ed), *New Technologies and Human Rights* (Oxford University Press, Oxford 2009), 179.

[148] European Commission, above, n 11, 20. Emphasis added.

[149] EGE, above, n 11, para 5.4.

manage'.[150] This has the effect of further limiting the potential for regulatory publics, in that publics themselves are regulated by virtue of the narrowness of discursive space within which they could feasibly operate. This presumably reinforces the bias, noted above, towards inclusion and voicing of certain ethical stances (over and above others). Indeed, as Brownsword remarks, once a 'technology has been pronounced safe, or at any rate not demonstrably unsafe, the *weight of "expert" scientific opinion makes it difficult for dissenting voices to be heard*'.[151] The increasingly limited scope for participation, in spite of calls to integrate 'the societal dimension'[152] in risk regulation and an 'inclusive approach'[153] to responsible research, works to reinforce the boundaries of responsibility and accountability: citizen participation in the regulation of risk can thus be regarded as an attempt to produce shared responsibility in the event of failure.[154]

C. 'Engagement' as 'Education'

These concerns are followed by an apparent extension of risk to encompass broader yet still underspecified '[s]ocietal impacts' that 'need to be examined and *taken into account. Dialogue with the public is essential to focus attention on issues of real concern rather than "science fiction" scenarios*'.[155] This contains a model of EU citizens that imagines them to lack knowledge and be readily distracted by 'science fiction' rather than 'real' issues. Thus, the Nanotechnology Strategy implies a need for public engagement with science in order to focus on regulating societal anxiety and fear, and working with the wider foreclosure of what is 'at stake' and who is regulated into participation. This works to narrow the scope of debate: issues that are not 'of real concern' can thus be designed-out of potential technologies of participation. Nanotechnology innovators (i.e. those scientists and engineers seeking to develop nanoscience and nanotechnology in university and commercial settings) are presumably to be called on within this framework to innovate the shape of public discourse through the separation of the science from the 'science fiction'.

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[150] Brownsword, above, n 5, 119.
[151] Brownsword, above, n 5, 119. Emphasis added.
[152] European Commission, above, n 11, 19–21.
[153] European Commission, above, n 81, 8.
[154] O Lieven and S Maasen, 'Transdisciplinary Research: Heralding a New Dawn between Science and Society' (2007) 16 GAIA Ecological Perspectives for Science and Society 35; G Abels, 'Citizen Involvement in Public Policy Making: Does it Improve Democratic Legitimacy and Accountability?' (2007) 13 Interdisciplinary Information Sciences 103.
[155] European Commission, above, n 11, 3. Emphasis added.

The logics at work here are likewise reflected in the assertion that though the 'Commission is working hard to ensure that nanoscience and nanotechnologies can bring their benefits to the market while controlling their potential risks'. This requires 'significant efforts to *stimulate information sharing and dialogue* among stakeholders to build trust in these technologies'.[156] Such comments construct and regulate a rather passive public, designed merely to bring about the dissolution of public concern and the support of pro-innovation regulation.[157] In this light, participation can be seen as feeding directly into 'Europe 2020' goals by implicitly promoting the (future) consumption of nano-enabled products and services. In turn, public participation can be read as inter alia a technology to build trust in an uncertain domain of innovation.

Thus, in spite of references to 'dialogue' within EU documents on nanotechnology, this seems to mean a distinctly 'one way' communication of benefit in which public safety concerns are addressed. Arguably, publics need certain information and a level of understanding of the science before an enhanced contribution to regulation and research priority-setting can take place. However, a focus on ignorance and a need for education is problematic. It is supported by PUS initiatives (e.g. the Eurobarometer[158]) to justify and measure the success of broad educational projects. These techniques also support the notion that publics are in some way being involved in decisions from which they are physically absent. The questions asked are stimulated by anticipatory and promissory discourses, and the fact that responses are given serves to validate these expectations further—reinforcing the need for regulation. However, any 'deficits' in knowledge that the Eurobarometer indicate might also be regarded by some as evidence that more education is required. This might justify a pedagogical element within participatory techniques, further disempowering non-scientists and lending more credibility to expert opinion. From this perspective, technologies of participation can, paradoxically, be understood as deployable as a means of *decreasing* the (substantive) involvement of citizens in regulatory and priority-setting in innovation.[159]

The current EU model of participation not only potentially underestimates the knowledge of (nano)science and technology that citizens may have, but also reaffirms the technocratic rationalities that exclude them: if publics need to have some kind of expertise in order to be

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[156] 'Stakeholders and citizens': <http://ec.europa.eu/health/nanotechnology/citizens_view/index_en.htm>. Original emphasis.
[157] More broadly see: <http://ec.europa.eu/health/dialogue_collaboration/system/index_en.htm>.
[158] Above, n 104.
[159] Cf Brownsword, above, n 5, 126–30.

included in deliberation about regulation, some might ask, why not simply limit involvement to credentialed experts in the first place? Part of the explanation is, as suggested above, to do with sharing responsibility and diluting EU accountability. Accordingly, this focus on participation-as-education could be regarded as a counter-democratic move that builds in future obsolescence into the technologies that are produced to elicit and include public perspectives. In other words, the discourses that privilege experts in nanoregulation and power technologies of participation, and which actively seek to reconstitute citizens as such (i.e. to make them expert in some way), eventually renders the technologies themselves redundant (since, if successful, everybody becomes an expert—there is thus no need to consult educated publics since those already working in the nanotechnology field can be taken as having the requisite expertise to help shape regulation).

V. DISCUSSION

In this paper, we have considered the role of public participation in EU regulation of nanotechnology through a novel lens synthesised through insights emerging from law, regulatory studies, critical theory, and STS. Specifically, we have sought to understand participation as a form of technology, and then to highlight both what it does, and some of the norms and values designed into participatory techniques. In so doing, we have sought to cast new light on the ways in which citizens regulate science, and the ways in which they themselves are regulated in the process.

What, then, do technologies of participation do? As should be clear by now, in strict terms of nanoregulation: very little. The EU widely discusses citizen participation in the regulation and governance of technoscientific innovation and implementation, but this is not legally institutionalised. As such participation is a de facto rather than de jure form of governance: it comprises diverse techniques and practices, mandated by policy (i.e. formally non-binding) discourses that are often produced by associated bodies concerned with the implications of technologies (such as the EGE). However, in the case of nanotechnology at least, the actual regulatory power of citizen involvement seems limited. This is surprising given how the wider societal benefits of nanotechnological applications, such as emerging health and medical technologies, are 'talked up' as part of the reason for the EU's focus on nanoscience and technology in general and, in relation to that, the figuration of its citizenry. Of course, measuring the impact of participation is an empirical question of the kind which is outside the scope of the more normative analysis this paper has sought to advance. Yet, if citizen

participation is a relatively under-utilised and under-powered technology of regulation, what, then is its actual function?

A key role of technologies of participation is to further empower drives to innovate. This is achieved through the instantiation of expectations about the potential of nanotechnology to improve health and wellbeing through applications like emerging health technologies, and within sites, spaces, and fora that can amplify and embed this anticipatory discourse within diverse cultural products (e.g. television shows, radio programmes, film, novels, and newspaper articles). These expectations in turn justify participation (completing the circuit), especially in instances where actual or imagined risks are articulated. In this light, the role of citizen participation in regulation can be seen largely as a means of legitimating (and perhaps even stimulating) innovation through engagement with risk, uncertainty, and promise, and mediating accountability through shared responsibility.

Scientists and engineers are key cogs that turn the wheels of participatory technologies. Their involvement and expertise in nanotechnology implicitly configures 'lay' publics as inexpert, and thus in need of reassuring via education. Such education speaks to modernist values on the import of empirically derived knowledge and the salience of technological 'fixes' for societal 'problems'.[160] Innovation thus becomes re-problematised; 'should' and 'how' questions in nanotechnology as a general field come to combined and specified as: how should the science be regulated in order to foster innovation and enhance health, wellbeing, and the economy?

Employing participatory technologies as a means of manufacturing support for innovation aligns regulatory strategies with published EU goals to advance science and produce a knowledge economy built on innovation. In turn, this is an important means through which the heterogeneous assemblage of institutions, agencies, and MSs that constitute 'the' EU produce an identity that represents this as a singular body with aims and the capacity to actualise these (and thus as a powerful and competitive global actor). A focus on innovation for health further legitimates both the EU and those seeking to innovate. It is precisely because these values and sociotechnical imaginaries are 'built into' the policies and practices underpinning and structuring technologies of participation that they function in the way they do.

In sum, then, the EU actively shapes technologies of participation (and hence what they can do) through discourses of risk regulation and bioethics, which are aimed at leveraging uncertainty in scientific

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[160] R Brownsword and K Yeung (eds), *Regulating Technologies: Legal Futures, Regulatory Frames and Technological Fixes* (Hart Publishing, Oxford 2008).

knowledge and bringing the future into the present. Supporting this are particular configurations of science/citizen relations (including PUS). Together, these might serve to simultaneously mobilise, prioritise, and include certain hopeful and optimistic, and therefore narrow, publics, that are likely to be underpinned by, and which articulate through, human rights and utilitarian-based ethics. Conversely, the discourses shaping participation might also serve to marginalise and even exclude more pessimistic publics. That is, those individuals and groups that are likely to be underpinned by, and which articulate through, a dignitarian ethic. This renders resort to proceduralism as a means of producing legitimate regulatory decisions in pluralist societies (such as the EU) even more problematic, in that the discourses shaping the conditions of possibility for participation differently empower the perspectives comprising the 'bioethical triangle'. This raises the question: how can legitimate, inclusive, and fair decisions be produced when all voices are implicitly not included, or are marginalised, and remain unheard, because they are in effect designed-out?

Of course, in raising this question and making our broader claims, we do not deny that there may be significant democratic benefits to citizen participation. Rather, it is precisely because of this that we feel it necessary to explore how and why limitations exist. Further, we refuse an account of participatory techniques that figures the citizens that work within them as both lacking in agency and fully configured through the technocratic norms and values that are built into participatory techniques. Indeed, to do so would be to deploy a similar kind of 'deficit model' of citizen engagement to the one that we have been concerned to critique. Thus, our goal here is to suggest that it is the norms, values, and imaginaries constitutive of a genuinely democratic EU, and a body politic comprised of reflexive agents, that need to be more carefully designed and built into technologies of participation. This is antagonistic to current means of inserting publics within restrictive regimes that close down opportunities for dialogue and debate, or which frame these so precisely and narrowly that 'public participation' is less about producing regulatory publics, than publics that are regulated into providing 'public legitimation'.