Beyond the limits to governance

Beyond the Limits to Governance: New Rules of Engagement for the Tentative Governance of the Life Sciences

Catherine Lyall (corresponding author)

Science, Technology and Innovation Studies, The University of Edinburgh, High School Yards, Edinburgh, EH1 1LZ, UK

Email c.lyall@ed.ac.uk

Telephone +44 131 650 2452

Joyce Tait

The Innogen Institute, Science, Technology and Innovation Studies, The University of Edinburgh, High School Yards, Edinburgh, EH1 1LZ, UK

joyce.tait@ed.ac.uk

Abstract

'Governance' is a highly plastic concept that has spilled over from the political sciences and has been adopted, in some cases rather uncritically, by scholars from other social science traditions. We argue that there are limits to this all-pervasive notion of governance. Some of these limitations could potentially be addressed by the 'tentative governance' approach if it can create new opportunities for learning in order to cope with the problems of uncertainty at an early stage of new and emerging technologies in areas such as the life sciences. In order to move beyond these limits, we may be able to use the heuristic device offered by tentative governance as a step towards developing and adopting new rules of engagement. These new rules of engagement need (i) to recognise that consensus may not always be possible in areas of new and emerging technology and (ii) to accept a more balanced approach to governance that acknowledges the role of policy and politics. In order to achieve this, we need to go beyond science and technology studies (STS) and innovation studies and adopt a more interdisciplinary approach that acknowledges the contributions already made to this governance debate by a wide range of scholars, including those in the political sciences.

Keywords: Governance; life sciences; consensus; public engagement

Highlights

- Examines the concept of tentative governance in the context of the life sciences
- Presents two case studies of tentative and adaptive governance
- Proposes guidelines for Constructive Stakeholder Engagement

1 Introduction

In the governance of emerging science and technology (EST), we are searching for and applying new approaches to cope with the problems of uncertainty. Kuhlmann et al. (this issue) propose a number of roles and modes of 'tentative governance' – namely that it is generally provisional, flexible, revisable, dynamic and open in its approaches, which include experimentation, learning, reflexivity, and reversibility – in order to tackle the uncertainties that are accentuated by the highly dynamic nature of EST.

This means that, as noted by Kuhlmann et al. (ibid.), tentative and more traditional forms of governance and government tend to co-exist and to co-evolve. The contemporary governance of science, technology and innovation in many countries thus oscillates, with experimentation in novel forms of governance but at the same time we would suggest, a possible retrenchment to more stable modes of 'government'.

We share Kuhlmann et al.'s understanding of the different forms of governance and its hybrid nature. However, given the intensely politicised nature of some of the engagement and dialogue initiatives undertaken as part of the governance process, linked in some cases to the social amplification of uncertainty (Stirling, 2014), the aim of tentative governance to be 'neutral in normative terms' may be difficult to realise in practice. Also, in developing our practice-oriented approaches to governance (generating analysis, diagnosis, policy impact and intervention), we are working in the zone where a tentative approach is challenged by pressures from innovators for clarity, consistency and stability in the regulatory environment. We draw on evidence from case studies of governance in action in the life sciences to argue that, in addition to the heuristic device based on the concept of tentative governance, policy tools need to provide guidance on making the transition from tentative governance to more 'adaptive governance'.

What is significant about our paper is that it offers a counterbalance to the prevailing, often-optimistic view, of the role of participation in governance. We build on the concept of

'tentative governance' by, first, advocating the need for a shift in the governance mode as an innovation moves away from upstream scientific research towards the development of new products and processes, and, secondly, calling for a *second generation* of governance approaches. We argue that, in some circumstances, this requires a more adaptive, practice-oriented approach to governance than that typically advanced by science and technology studies (STS) and we draw on empirical evidence from case studies to propose a novel set of guidelines for such an approach.

The paper is structured as follows: Section 2 evaluates previous governance approaches presented in the literature and offers a critique of first generation governance in the context of life science innovation. We highlight some of the challenges of participation and engagement and the questionable goal of consensus. In Section 3 we briefly describe our methodology and Section 4 presents two case studies from which we derive and test guidelines relevant to the tentative approach (Section 5). In Section 6 we assess the extent to which the concept of tentative governance might move beyond a heuristic device to a workable policy tool in order to deliver a more democratic, governance-based approach to life science innovation.

2 The limits to governance

2.1 Tentative governance in the context of the life sciences

A generation ago, when we considered the relationships between science and society we did so through the lens of 'science policy', a complex, multidisciplinary endeavour encompassing scholars from, *inter alia,* economics, sociology, politics and the machinery of government. Now when we consider this relationship, we are more likely to talk in terms of 'the governance of science' and, indeed 'the governance of science *and innovation*'. The focus has shifted from a predominantly political and economic context for science to a more sociological one; one that draws in not just a different set of public actors but a different

scholarly community, and addresses more downstream issues related to innovation processes rather than fundamental research.

A tentative governance approach offers flexibility and creates opportunities for learning in order to cope with the problems of uncertainty at early stages of research on new and emerging technologies. The focus of this paper is innovation in the life sciences, a field that is subject to a broad array of inherent uncertainties related to scientific background, technological shape, applications and the resulting economic and societal benefits and risks (Kuhlmann et al., this issue). New actor constellations and practices related to knowledge production, innovation and societal appropriation have emerged and largely differ from those of established technologies. This poses specific challenges to the governance of the life sciences, which has to cope with ill-defined, controversial and sometimes moving targets. As such, simply broadening decision-making does not obviate the need for political judgements (Lyall et al., 2009b; Lyall, 2007), particularly at more downstream stages in development processes (Tait, 2017). There is also a need to develop strategies and procedures to help decision-makers to govern science, technology, risk and the environment in a way that makes best use of appropriate systemic analyses on the basis of the best available evidence from both social and natural sciences (Lyall and Tait, 2005, p.186).

As described in the Introduction to this Special Section, 'governance' is generally regarded as implying an increasingly complex set of state-society relationships where networks rather than hierarchies dominate the policy process. This rather broadly-conceived term is viewed as a mechanism for mobilising political resources in situations where these resources are widely dispersed among public and private actors, and as a specific form of public-private non-hierarchical interaction (Börzel, 1998). Although the associative model, as a way of thinking about state-society relations, is relatively pervasive in the European literature, Anglo-American countries are traditionally less accepting of the role of social actors in governing (Peters, 2014). British authors have historically approached the policy network

paradigm as a form of 'interest group intermediation' (a generic term for all types of relationships between interest groups and the state) whereas German and Dutch scholars (for example, Kooiman, 1993; Mayntz, 2003) relate governance to wider issues of deliberation and civil society development and to legitimacy problems of government. These different scholarly traditions result in rather different emphases on governance: on the one hand a more adversarial approach that negotiates between interest groups and, on the other a collaborative, inclusive model.

Political scientists have long questioned the validity of the governance approach (e.g. Marinetto 2003; Thompson 2003; Davies 2011). In reality, governance processes can be quite exclusive, closed to outsiders, unrepresentative, unaccountable, difficult to steer and can reduce the opportunities for open democratic debate (Bevir and Rhodes 2003, p.75; Greenaway et al., 2007; Sorensen and Torfing, 2009; Tait and Barker, 2011). Consultations can diminish accountability, as compromises are negotiated between interested parties outside established political processes and institutions (Barry, 2001; Hagendijk and Irwin, 2006). Networks may only cohere around a problem when people have already taken entrenched positions (for example, the GM crops debate in the EU) (Sunstein, 2009). So a governance approach can also *limit* participation in the policy process and may channel it in the direction of greater confrontation.

While the history of governance during the 20th century may appear as 'a shifting balance between government and governance' (Rhodes 2007), this should not be interpreted as a steady, uniform, linear progression from government to governance (Lyall et al., 2009b). Kuhlmann et al. (this issue) contrast *'tentative modes of governance'* with *'definitive modes of governance'*, suggesting that we might find different degrees of governing more or less *intentionally* and *incidentally* such that *'*a definitive governance initiative might finally turn out to develop de facto in a tentative way, and a consciously chosen tentative approach might unfold in a way that urges key actors to take tough top-down decisions'. But this notion of

hybridity is not especially novel (see, for example, Peter, 2014). Indeed, one of the main protagonists of the 'hollowing out of the state' concedes that 'the traditional instruments of government co-mingle, compete and conflict with the new instruments of governance to variable effect' (Rhodes 2007). Rhodes (ibid.) also admits that 'the policy networks literature pays too little attention to change' and this is a serious omission in a fast-moving policy field such as the life sciences where policy and regulation often struggle to keep pace with the science (Tait et al. 2006, 379).

2.2 Exploring governance – engagement interactions

If we are to explore the notion of tentative governance in practice, we need to reflect on experience and draw lessons for the next generation of governance of EST. Governance, regulation and public engagement have become intimately linked such that, when there are cases of regulatory failure, the automatic response is to demand greater engagement. But there are serious limitations in the context of the life sciences when 'bottom up' governance is required to operate within a 'top down' regulatory system. Engagement within such a structure pushes groups to extremes and causes turbulence within the system. This demands that we think further about how to 'do' governance in a context of increasingly complex and sometimes conflicting public perspectives.

The governance perspective might just be 'a simplifying lens to a complex reality' (Stoker 1998) but policy-makers at all levels believe that improved public participation in the policy-making process will create more confidence in the resulting policies and ensure more effective implementation. Much has been written about public participation as a new tool of governance but public engagement is only one of many influences on the decision-making process. A governance gap exists in the translation between public engagement and policy-making/regulation: the peril of focusing primarily on engagement is that it ignores the underlying complexities of governance.

In the UK there have been three defining moments along the trajectory of public engagement beginning with the Bodmer report (1985), which characterised the issue as a lack of public understanding of science ('the deficit model'). The turn towards 'dialogue' came in 2000 with the publication of the 'Science and Society' report (House of Lords, 2000), followed four years later with a bold move to bring public engagement 'upstream' (Wilsdon and Willis, 2004). At each point in this trajectory there was a broad range of different ideas, values and interests fighting for dominance.

This period has witnessed a mainstreaming of public engagement in EU research policy. In the UK this has led to public funding formalised through, for example, Sciencewise and Research Councils UK[1] and, in turn, the widespread institutionalisation of public engagement work and a burgeoning academic literature on public engagement. These heterogeneous visions of the governance of science in society, which assume a weak role for government, require that 'more complex visions of governance than simply producing a formal input to the government policy process need to be envisaged' (Felt and Fochler 2008). Upstream engagement has been described by its critics as offering 'compressed foresight', whereby highly uncertain socio-technical prospects are presented as imminent and known (Williams, 2006). The complex interdependencies and optimal level of decision-making demanded by life science innovation risk becoming subsumed, if we simply equate 'governance' with 'public engagement'.

The argument for upstream engagement has been that we failed to engage effectively with the public in the development of GM crops and that in future, citizens should have a say in the basic funding of science, not just its application. This argument was widely accepted among scientists who saw it as a way of convincing the public of the value of what they do (Anon, 2004). If well conducted according to appropriate rules of engagement, it was

[1] www.sciencewise-erc.org.uk (last accessed 10/12/18); RCUK has now become UK Research and Innovation (UKRI). An archived copy of the RCUK website is available from the National Archives: http://webarchive.nationalarchives.gov.uk/*/http:/www.rcuk.ac.uk/

claimed, such a process could help to improve the quality of the dialogue among a wide range of stakeholders on issues related to the development of new technologies.

In practice, there are problems of applying upstream engagement to the life sciences in terms of our foresighting abilities related to innovation outcomes and the biases that are inevitable in most stakeholder engagement processes (Tait, 2009b; 2014). Also, conflict related to life-science developments will inevitably arise from a complex mixture of uncertainty, power politics, divergent societal interests, values and ideologies, and commercial competition. Upstream engagement can create opportunities to reinforce the negative framing of new technologies such as nanotechnology or synthetic biology where, for many questions, there will be no societal consensus about whether we should develop particular technologies. This may lead to a lack of tolerance of alternative views – a form of counter 'capture' of public interests. This perceived de-professionalisation of science decision-making leads to decisions based on opinion rather than the best available evidence of potential benefits and risks (Collins, 2009).

The UK Government Office for Science's resource centre for public dialogue, Sciencewise, conducted an international comparison of public dialogue on science and technology (Sciencewise, 2010). Their report acknowledged the challenges of evaluating the impact of such public dialogue on the policy-making process and recognised the need for more discussion about the uncertainty inherent in the scientific research process. This report recognised the democratic challenges of such a governance approach, including the suggestion that 'we need more public debates which acknowledge the uncertainty inherent in novel S&T developments, and move away from traditional positional debate'. The report also highlighted the 'difficulty (and cost) of initiating and sustaining large-scale dialogues on science and technology issues which can be said to genuinely represent the views of the general public, and which have clear links to policy-making' (Sciencewise, 2010, p.50).

2.3 Consensus: an unattainable goal

A democratic system is defined by its openness to all but does not require the participation of all the people all the time (Stoker 2006, p.154). The complexity of the relationships between state and non-state actors may make it difficult for citizens to understand how legitimacy and accountability function. The challenge of a governance approach is that it may invite non-accountable actors into the processes of steering (Pierre and Peters 2000, p.67). Deliberation and public engagement may be presented as a democratic route to consensus formation, such that 'once the public understands the 'real' issues, then it will trust institutions, a 'reasonable' consensus will arise, and policy-making can proceed' (Hagendijk and Irwin, 2006). However, these authors warn that too great an emphasis on consensus can lead to a sense of exclusion amongst groups that disagree with the framing of the debate. In policy debates related to the life sciences there is a potential for engagement to be dominated by strong, ideologically-based opinions and in plural democracies it may not be possible or desirable to reach a consensus.

Shifting the emphasis from expert groups to advocacy groups (whose views may be based predominantly on interests and values or ideology) has the potential to lead to an imbalance of power that has no basis in balanced evidentiary standards (Wagner, 2005; Tait and Barker, 2011). While participatory processes are important 'to the project of democratizing technology', 'there can be no automatic presumption that they will necessarily be sufficient, or even always positive, in their effects' (Stirling 2008). Indeed, dialogue may not insure against future public protests: many would argue that the backlash against GM was not a consequence of a lack of dialogue between scientists and their publics, or 'some kind of spontaneous outpouring of public anger against 'Frankenfoods' but the result of a well-orchestrated campaign by an alliance of NGOs (Anon 2010; Tait, 2001).

We do need to be able to recognise the potential for value-based conflict (Bruce, 2011) at an earlier stage in the technology trajectory and to create spaces where these aspects can be

explored as the trajectory develops: but, in such cases, 'the relevant science can never be settled to the satisfaction of all parties – it is always going to be politicized' (Sarewitz 2010). Where values are a key element in dialogue, we should not ignore them nor force them to be expressed in terms of 'scientific evidence' but rather we should find a lexicon for talking about them openly in the same way that we now do about 'risk' (Laurie et al., 2009).

The conventional view is that participatory methods are more 'democratically progressive' when linked directly to decision making (Stirling 2008) but Walls et al. (2005) caution against romantic interpretations of governance as indicating a 'uniform popular trend towards the democratisation of state decision-making'. Rather, they suggest that a more plausible account is provided by seeing governance as a form of 'adaptive management necessitated by a series of interlocking economic and social changes, and responses to successive risk management crises'. So, a governance approach may have gone too far if we neglect the legitimate role of the state and elected decision-makers in decision-making.

Public dialogue about the sort of society in which we want to live is to be encouraged and upstream engagement has brought new voices to decision-making, including activist groups working through NGOs. This has been matched by a decline in the influence of industry and other professional groups. Moreover, the voice of 'ordinary citizens' (or the 'innocent citizen': Irwin, 2006) is not necessarily being heard (Tait 2009b). These new approaches to decision-making may be no more democratic than before; and the challenge for the future governance of the life sciences remains how best to incorporate the most useful aspects of governance-based approaches and reconcile them with the still necessary system of regulation to ensure product safety and efficacy so that the focus on the 'public' does not exclude the legitimate behaviour and motivations of others such as industry, scientists, policy makers and regulators.

Irwin (2006) speculates that 'uncritical treatment of current science–public interactions might lead to an equally uncritical backlash when policy expectations of public consensus and

support are (almost inevitably) disappointed'. For Mouffe (2000)[2], democracy is better seen as inherently antagonistic, rather than as oriented towards consensus building and deliberation. From this perspective, political struggle about the boundaries of government is not a drawback of democracy, and public engagement will always be framed in a context of contested relations. Instead, we may need to learn to embrace 'clumsy solutions' which have sought to combine opposing perspectives in other complex policy areas such as climate change (Verweij et al. 2006).

3 Method

Our work with the UK Economic and Social Research Council (ESRC) Genomics Network, particularly through the Innogen Centre and now Innogen Institute has enabled us to observe, and in many cases, gain access to and participate in a number of engagement and regulatory initiatives related to the governance of the life sciences and other technologies. Examples include the GM Nation? consultation; the Nuffield Council on Bioethics review of biofuels; the Food Standards Agency GM dialogue; the Emerging Science and Bioethics Advisory Committee (ESBAC); the Synthetic Biology Leadership Council (SBLC); the annual report of the Government Office for Science (Walport and Craig, 2014)[3]; and the British Standards Institution-funded projects on Proportionate and Adaptive Governance of Innovative Technologies (Tait *et al.*, 2016, 2017)

Spurred by the premise of 'starting where you are' (Lofland and Lofland, 1995), this has enabled us to develop a long-term ethnography using document analysis alongside personal participation in a series of governance related initiatives to construct two case studies of the governance of the life sciences (Section 4). These cases demonstrate how both tentative and adaptive processes of governance have been, or could be, applied by focusing on the

[2] Quoted in Hagendijk and Irwin (2006).
[3] http://www.gmnation.org.uk; http://nuffieldbioethics.org; http://webarchive.nationalarchives.gov.uk/20120206100416/http://food.gov.uk/news/newsarchive/2009/nov/gmdialogue; https://www.gov.uk/government/groups/emerging-science-and-bioethics-advisory-committee; https://connect.innovateuk.org/web/synthetic-biology-special-interest-group/synbio-leadership-council (all accessed 10/12/18)

need to achieve a balance among competing societal influences and power bases, values and ideologies, and commercial competition. Using the material derived from these cases, we have tested principles or 'new rules of engagement' for tentative and adaptive governance of innovative technologies (Section 5), potentially demonstrating how these concepts could be implemented in the context of the life sciences.

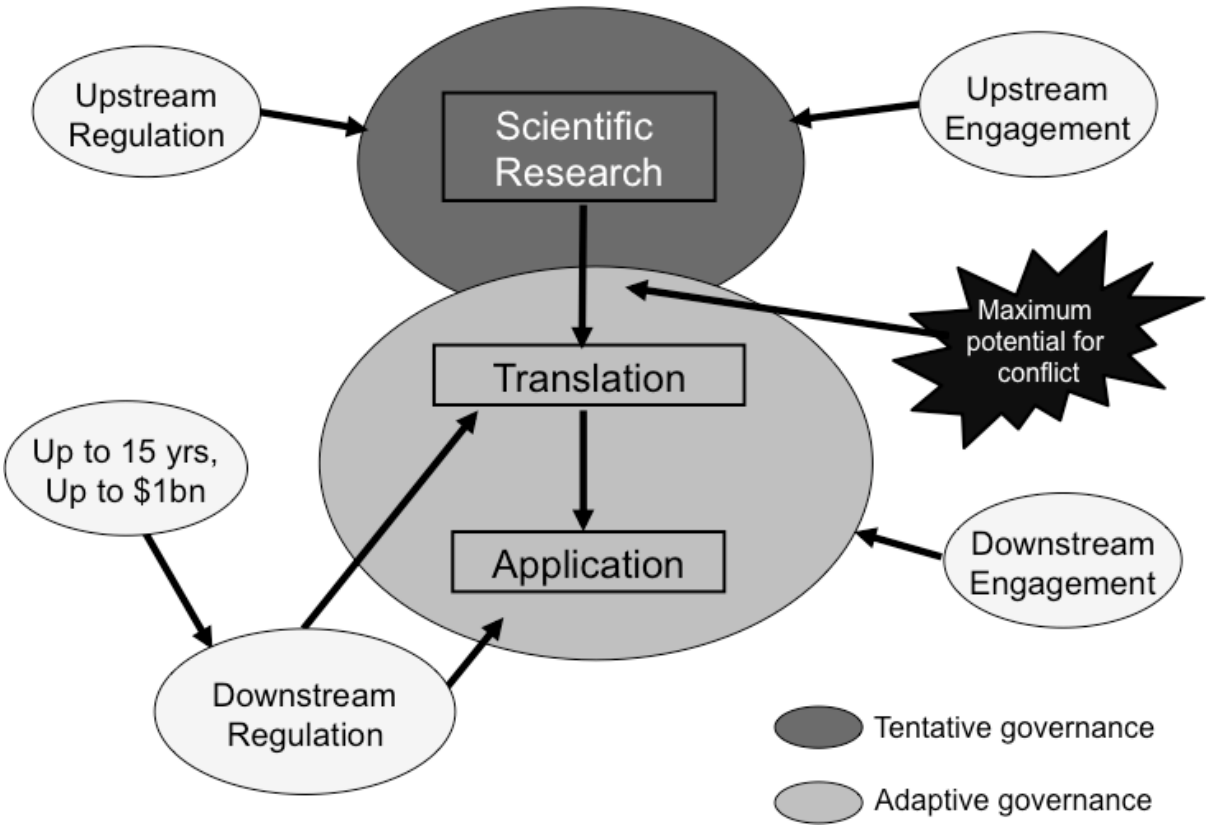
As noted above (Section 2.1), different national traditions imbue governance with different emphases. The political economy and historical context play a significant role in shaping the political system and this, combined with the nature of our engagement through the ESRC Genomics Network, justifies the paper's specific focus on the UK and, to a slightly lesser extent, the European Union.

4 Case studies of tentative and adaptive governance

Figure 1 demonstrates how we envisage the relationships between tentative and adaptive governance in the bio-economy where innovation is usually constrained by the need for a lengthy and expensive regulatory system, involving top-down 'government' in order to ensure safety and efficacy of novel products and processes. Past experience has shown that the transition stage from upstream research to downstream technology development is most likely to be the flash-point for the emergence of societal conflict about contentious new developments.

We argue that 'tentativeness' is the appropriate mode of action in 'upstream' stages of scientific research where much is still being learned about whether a product or process will work as expected and what kinds of technology will emerge. In some cases at this stage it will be appropriate to adopt a precautionary approach, although this should not be

Figure 1. Tentative and Adaptive Governance



automatically assumed. Beyond this point, if there are plans to develop a technology further, there is increasing pressure on regulators to reach decisions about the appropriate regulatory precedent for the new technology. This should be based on the best available evidence about its opportunities and risks, and the decision-making process should be focused but flexible and adaptive to cope with new information about benefits and risks that emerges throughout the development process. The aim should be to ensure that unnecessary, unrealistic constraints are not imposed on innovations that meet urgent societal priorities.

These case study examples illustrate our proposition that tentative governance, embodying an approach that is provisional, flexible, reversible, dynamic and open, with a focus on

uncertainty, is very well suited to the challenges of governance at the upstream stages of development when the main focus is on stakeholder engagement and where upstream governance should involve experimentation, learning, reflexivity and reversibility. As an innovation moves further downstream, the governance approach will increasingly interact with top-down government and pre-existing regulatory systems and the governance approach will need to become more 'adaptive', implying a more controlled approach to delivering useful innovation in a societal context, and the need for more downstream engagement that brings in stakeholders with a more direct interest in the innovation being developed.

4.1 European Advanced Therapy Medicinal Product Regulation

The approach taken to the development of the European Advanced Therapy Medicinal Product (ATMP) Regulation[4] could be seen as an example of tentative governance. At each stage, from initial concept in 2002, through various steps in intense consultation with interested parties, discussions at European Council meetings amongst the 27 Member States, ratification during a single reading in the EU Parliament (2007), implementation of the Regulation at the European Medicines Agency (EMA) (2008) and operation of the Committee on Advanced Therapies in January 2009. At each of these stages, the results of consultation with the interested parties resulted in modifications to the documents[5].

In addition to the Regulation, which was drafted on the basis of high-level principles, to allow flexibility as the science evolved, guidelines were developed by the EMA and the European Commission to provide more detail of the requirements for Marketing Authorisation Applications (MAAs), and again these were put out for consultation with all interested parties. Thereafter, the documents were finalised. The guidelines were prepared to explain in substantial detail the scientific data requirements for MAAs. Again, at each of the

[4]http://ec.europa.eu/health/human-use/advanced-therapies/index_en.htm (accessed 13/12/18); http://ec.europa.eu/health/human-use/advanced-therapies/developments/index_en.htm (accessed 13/12/18)
[5] Private communication, 11 December 2012.

consultation stages, the results of such exchanges with the interested parties resulted in documents being modified.

Throughout the period from 2002-2008, from concept to the implementation of the regulation, consultation with interested parties was intense to allow all to comment. In view of the need to incorporate representatives from the Medical Device Sector at an early stage because of the use of devices in tissue-engineered products etc., steps were taken to consult with them so that their observations could be taken into account. The effectiveness of this 'tentative' approach taken by Dr Paul Weissenberg (Deputy Director General of the DG Enterprise and Industry of the European Commission), and the Commission, thus led to the notable event that, at the time, this Regulation was the only one that had passed through the European Parliament in a single reading.

As noted above (see Figure 1), tensions are more likely to emerge at the point when innovations move from upstream to downstream governance phases. So, despite intensive consultation and engagement, serious difficulties emerged in application of the ATMP regulations to the downstream development of a range of medical innovations, demonstrating the need for regulatory choices to be adaptive in the face of the emerging characteristics of the new technology (Marazzi, 2013; Tait *et al.,* 2017).

For example, the choice of the ATMP Regulation as the appropriate precedent to be applied in regulating regenerative medicine and cell therapies, widely consulted on with stakeholders at the upstream stages of development of this technology, opened up challenges requiring a considerably more adaptive approach to its downstream implementation than was initially realised. During its development, the ATMP Regulation was not adapted to deal with living human cells, leaving in place the requirement to test products first on animals and creating a major challenge to adapt the system to derive meaningful results from such an approach or to find an alternative route to these early tests for product safety (Mittra et al., 2015). This choice also created the expectation that the therapeutic end products would be delivered by

multinational pharmaceutical companies, although they were path-breaking for the pharmaceutical sector, leading to on-going reluctance of these companies to invest in this new technology (Tait, 2007a) and difficulties in finding viable business models for future product development (Omidvar et al., 2014).

4.2 Nuffield Council on Bioethics (NCOB) Reports

The NCOB was funded by the UK Medical Research Council, Nuffield Foundation and Wellcome Trust to identify and define ethical questions raised by advances in biological and medical research in order to respond to, and to anticipate, public concerns, to promote public understanding and discussion, leading where necessary to the formulation of guidelines by the appropriate regulatory or other bodies. Two reports from the NCOB illustrate contrasting approaches to achieving a balance among the interests and values of stakeholders: (i) 'Emerging Biotechnologies: technology, choice and the public good' (NCOB, 2012) takes a clearly tentative approach to governance and focuses on the ethical issues relevant to upstream research and (ii) 'Biofuels: Ethical Issues' (NCOB, 2011) takes a more adaptive approach to governance and focuses on issues raised in the downstream development of biofuels. The Working Parties charged with producing these two reports carried out public consultations over a period of several months to obtain views from as wide a range of interested parties as possible and received 80-90 responses. Each also held a series of evidence-gathering workshops with scientists, social scientists and policy makers. The Biofuels Working Party held two additional workshops with industry and with civil society groups. Although the two working groups adopted similar procedures, and the reports reflect the need to balance the views of the wide range of constituencies consulted, their conclusions reflect the different stages of development of technologies being addressed.

The recommendations arising from the 2012 Emerging Biotechnologies Report focused much more strongly on research policy and science funding and less on the potential ethical challenges, costs, risks and benefits of products and processes arising from novel

technologies. The general approach adopted was congruent with a tentative governance approach. It proposes that governance should be guided by a 'public ethics' approach to addressing the question of how society should determine the conditions through which to foster socially and ethically responsible innovation in biotechnology. The public ethics approach, as with the Biofuels Report, refers to the underlying values of equity, solidarity and sustainability, but with a much stronger focus on future visions for emerging biotechnologies and avoiding an 'optimism bias' for prospective technologies. Emerging biotechnologies are seen to pose three challenges – uncertainty, ambiguity (i.e. they can be valued in different ways in different contexts), and transformative potential (i.e. they can change common ways of life and open up new ranges of possibilities). In thinking about these three challenges, the framing of governance questions is seen to have a significant impact on how biotechnologies are developed. This observation will have implications for the strong emphasis of this report on public engagement in contributing to a more ethically robust public decision-making process.

The 2011 Biofuels Report included both currently available biofuels and those that may emerge in future based on new scientific discoveries, taking account of concerns about energy security, economic development and climate change and a need for an adaptive governance approach in the contexts of public policy and targets for the introduction of biofuels. Five ethical principles were proposed that should be met in the development of biofuels related to: the protection of basic human rights; contributing overall to environmental sustainability; contributing to a net reduction in greenhouse gas emissions; recognising the rights of people to just reward; and distributing the costs and benefits of biofuels in an equitable way. An unusual balancing feature in this report was the addition of a sixth principle: if the first five principles are respected and if biofuels can play a crucial role in mitigating dangerous climate change then, depending on certain key considerations, there is a duty to develop such biofuels (Buyx and Tait, 2011). The key considerations envisaged included the requirement that the process was economically viable in competition with other

approaches to climate change mitigation. Such balancing caveats are often implied in ethical discourses but they are rarely stated so positively.

These two NCOB reports exemplify the difference between tentative and adaptive approaches to governance in dealing with innovation in the life sciences. The Emerging Biotechnologies Report focused more on upstream issues, uncertainty, precaution and broad ranging stakeholder engagement as a basis for policy decision making. The Biofuels Report on the other hand focused on more downstream issues, emphasising quantitative analytical evidence as a basis for decisions on sustainability of biofuel developments and considering how evidence could be acquired as a basis for decision making on the ethical aspects of biofuel development, rather than undertaking formal public engagement as the primary basis for such decisions.

5 'Second generation' governance – adaptation and new rules of engagement

5.1 A more interdisciplinary approach

In the context of EST, governance is about managing complexity and 'finding the optimal level of decision-making and dispersion, power and legitimacy, participation and action' (de la Mothe, 2001). In the UK, the notion of governance finds its antecedents in work on advocacy coalitions, New Public Management and participatory democracy. This literature was grounded in studies of privatisation in the 1990s; the loss of central and local government departments to private sector delivery systems; and a shift from British government to EU institutions. While the focus was on relationships that spanned the boundaries between the public and private sector, and between administrative units within government, it clearly did not address the specific challenges of applying it in the context of new and emerging technologies.

Many sociologists of science and other scholars aligned with the discipline of Science and Technology Studies (STS)[6] have adopted the lexicon of 'governance' as an approach to navigating and understanding the complex and dynamic arena of science-society relations. STS has espoused the terminology of governance in the context of new technology and, in particular, innovation in the life sciences without, in many cases, engaging with the critical self-reflection undertaken by political scientists of the limitations of network governance theory.

Within STS, public engagement has largely become a synonym for governance and has attained a potent orthodoxy. The social sciences' engagement with the life sciences has typically been modulated through 'ELSI' (ethical, legal and social implications)[7], which casts social scientists variously as advocates, translators, critics, activists, reformers (Calvert and Martin, 2009) or intermediaries in the mobilisation of public sentiment (Williams, 2006). This tends to position them as mediators rather than scholars in their own right (Rip, 2009) and may limit their role to one of public/stakeholder engagement. While reflexivity is important, past efforts may have shifted the balance too far in this direction (Rip, 2009) and, as Williams (2006) notes, 'this somewhat privileged position places a special responsibility on STS researchers to consider their commitments with great care.' The expertise required for conducting participatory exercises needs to be 'both conscious and critical of the visions of science, society, governance and participation' (Felt and Fochler, 2008). Furthermore, it needs to take the performativity of these methods seriously 'rather than being committed to a naïve ideal of neutrality' and efforts to develop more substantive modes and formats of engagement 'need[s] to be accompanied by a critical debate on the expertise of the community' (Felt and Fochler, 2008; also Rose, 1999). This theme is taken up by Webster (2007) in calls for a more 'serviceable STS' that can engage effectively with policy making while retaining a critical and independent perspective. While a more traditional, government

[6] See Fagerberg et al. (2012) and other articles in that issue of *Research Policy* for a discussion of the emergence of STS as a discipline.
[7] And now ELSI 2.0 (Kaye et al. 2012).

approach expects advisers to take a neutral role equivalent to that of Pielke's 'honest broker' (Pielke, 2007), the *governance* approach has encouraged issue advocacy and, at times, stealth advocacy (Tait, 2017): the time may indeed have come for the STS community to find a relationship to public engagement that moves beyond criticism alone (Irwin et al., 2013).

The shift to governance further means that the science policy literature now bridges the more positivistic traditions of political science and the interpretive, socially constructed approach taken by those in STS. A core element of this approach has been the development of 'public engagement' both as an object of study and, in many cases, a form of action research. Irwin (2006) suggests that we must move away from the orthodox science and technology studies defence of public participation and citizen-science engagement towards 'an analytically sceptical (but not dismissive) perspective on the new mode of scientific governance'. Engaging in a wider dialogue across a wider range of social science disciplines and professional functions would bring in expertise in innovation systems, regulation, governance and economics.

Some authors call for a 'second generation' approach to governance (e.g. Rehmann-Sutter, 2012) and this again throws different disciplinary approaches into relief. Within the political sciences literature, 'second generation' governance theory has been concerned with the legitimacy of evolving governance structures, including partnerships and networks, and contrasts representative democracy with the interactive model, which is essentially deliberative in nature (Barnett 2011). As Barnett notes, a key critique of the deliberative approach has been that it is extremely difficult to operationalise and 'uncontaminated' deliberation is virtually impossible to achieve. Bevir and Rhodes (2010) describe this second wave of governance as 'metagovernance' where the state co-ordinates self-regulating governance mechanisms and acts, in the case of governance failure, as 'accountable body of last resort' (Davies 2011, p.19).

5.2 Constructive stakeholder engagement

Stakeholder engagement is one of the main platforms of a tentative governance approach and this paper proposes that tentativeness in governance, with its focus on engagement and uncertainty, is a desirable characteristic during the earlier stages of scientific research when it is still unclear what will work in scientific and technological terms, what kinds of novel products and processes will eventually reach a market place, and how they will be perceived by various stakeholder communities.

Questioning the hegemony of public engagement may not be fashionable. Nevertheless, in their essay looking back on the two decades since the journal *Public Understanding of Science* was launched, Stilgoe et al. (2014) acknowledge that public engagement would seem to be 'a necessary but insufficient part of opening up science and its governance'. In their role as public engagement practitioners, they concede to 'over-promising' and recognise 'a collective failure to take politics seriously' (ibid.).

We are not advocating a return to the economically-dominated model of science policy of the 1980s and 1990s but sustaining tentative governance networks and undertaking public engagement exercises are resource intensive endeavours. If we are to undertake meaningful engagement in debates about EST, then we must surely aspire to do it in the most effective manner. For Stilgoe et al. (2014), the focus is shifting from 'why' we promote public engagement with science towards 'when', while for others the important question is 'how' actors work together to provide governance (Peters, 2014).

In developing our case studies, we have identified the need for a more constructive approach to stakeholder engagement than has generally been undertaken to date. The guidelines proposed in Table 1, operationalise the ideals of tentative governance in being provisional, flexible, revisable, dynamic and open. These guidelines have been distilled from our experiences in the above examples and a range of other case studies (Tait and

Chataway, 2010; Tait et al., 2007a,b; Tait, 2007b) with the aim to make stakeholder dialogue more constructive in potentially contentious areas of life science innovation, dealing with issues of public choice and stakeholder engagement in contributing to regulatory decision-making within a democratic system.

Unless managed well, tentative governance in upstream engagement processes (where the science and technology are still subject to considerable uncertainty), has the potential to generate conflict and polarisation (Sunstein, 2009) and to jeopardise the development of societally useful technologies further downstream (Tait, 2009b). Where stakeholders, of whatever complexion, are involved in formal engagement it is helpful to have such guidelines to set standards for the equitable and balanced conduct of the process (Tait *et al.*,. 2018).

Table 1: Guidelines for Constructive Stakeholder Engagement

1. Discussions should be open and accommodating of the full range of relevant opinions (general public/citizens, scientists, industry, users of the technology, consumers) and no single perspective should expect to dominate other opinions or to dictate the terms of engagement
2. Engagement should be carefully timed: too early (upstream) and its value will be undermined by uncertainty about the nature of future developments; too late and stakeholder opinions and political positions may have become entrenched so that accommodation will be more difficult to achieve
3. Where views are strongly polarised, engagement will not necessarily lead to consensus and expectations that all stakeholder views can be accommodated will not be met. Accept that consensus may not be attainable
4. Promote dialogue across a wider range of issues to include the processes by which new scientific discoveries are translated to products in a market place and how this process is regulated

5. Consider under what circumstances it is appropriate to leave it to market forces to decide what products should be available, rather than allowing the values and interests of one group to restrict the freedom of choice of others
6. Set standards for the quality and breadth of evidence that is brought to discussions about novel technologies and their regulation
7. Consider carefully whose precaution should be relevant to a decision, and what we should be precautionary about
8. Where there are conflicting values, be equitably sceptical about the impartiality of evidence presented in support of a case, particularly evidence contributed by organised groups representing commercial interests or NGOs
9. Where there is conflicting evidence, consider carefully the expertise of those promoting the evidence, including both scientific and experiential expertise, and weight it accordingly. Do not allow one interest group to have a degree of influence on regulatory standards that is not justified by evidence, to the detriment of other interests
10. Have a clear plan for moving to an evidence-based approach as experience with a new technology accumulates

5.3 Adaptive Governance of Innovative Technologies

Governance is still a 'relatively young instrument' in innovation studies, which assumes that solutions can be found for all conflicts and that diversity enhances the quality of decision-making (Nowotny and Testa, 2010). However, the lack of common values restricts decisions 'to the smallest common denominator' and the process is decoupled from the institutions of representative democracy (ibid. pp78-79). This emphasises the point that dialogue and deliberation are not equivalent (see, for example, Escobar, 2011). Participation does not

necessarily result in meaningful dialogue, nor is participation synonymous with decision-making. The two practices take place in different spaces and with different configurations of actors and, as noted above, while tentativeness in governance is a desirable characteristic during the earlier stages of scientific research, as new products and processes are developed and refined with specific markets in mind, the governance process will be under pressure to become more focused and choices will be made about the appropriate regulatory precedents for the new technology. Beyond this point, tentativeness is no longer a desirable attribute and the primary requirement of the governance approach is that it should be adaptive to changes in our understanding of the technology and its properties. The stakeholder engagement guidelines set out in Table 1 will still be relevant in this adaptive context, but there will be considerably less uncertainty about the risks and benefits of the technology involved and the topics taken up in the dialogue will (or should) be more about how the technology should be implemented, how it should be regulated and who should reap the benefits.

Much of the focus on public engagement has led to governance in the absence of government and this has limited its effectiveness. In the life sciences, when dealing with uncertainty in the face of rapidly changing technologies, we have shown that governance cannot take place without government (Lyall et al. 2009b). The governance shorthand misleadingly assumes that governance is a homogeneous entity or activity but this is clearly not the case in the field of EST. Moreover, this shorthand fails to address the governance gaps that persist between participation, deliberation and decision-making.

There can be a tendency for societal discussions about the desirability of life-science innovations to ignore the fact that the technology will be regulated and must be proven safe before it reaches the market (Tait 2009b; Tait, 2014). One value of a democratic governance process lies in its ability to prevent vested interests from dominating policy decision-making and to enable open choices for as many citizens as possible but policy

needs to be proportionate to the risks and benefits to individuals and to society, allowing for different applications depending on the context (Nuffield Council on Bioethics, 2011, p.78; Academy of Medical Sciences, 2011; Tait *et al.*, 2017).

None of the foregoing discussion implies that there should not be room for serious and intractable disagreements over the introduction of EST. Such debate is an important part of political processes but we argue that acknowledging some of the limitations of governance structures may enable a more constructive set of alternatives to emerge. We have to find appropriate times and appropriate ways of undertaking participation and then construct more transparent ways of conducting the deliberation.

On the one hand we are witnessing much experimentation with practices, institutional arrangements, regulations, and instruments but, on the other hand, there is also a move back to more stable modes of governance. As Kuhlmann et al. (this issue) note, certain forms of tentative governance 'operate in the shadow of hierarchy' not least because industries have often welcomed regulatory collaboration because of the stability, certainty and property protection that regulation can provide. When tentative modes of governance are introduced into public policy, Kuhlmann et al. therefore suggest that they are closely related to more stable and formal governance modes such as legislation. Clearly, the overlapping government/governance trajectory (Figure 1) acquires new degrees of complexity in the context of the life sciences where the regulatory time-scale is greater than ten years, costs more than $500 million, where market choices are usually not made by individual citizens, and where the nature of the science, itself, along with the products to which it gives rise are often publicly contentious (Tait, 2009a).

Within the context of EST, the governance-based approach was promoted in a spirit of optimism as a means to achieve more democratic and more robust political processes and decisions, distributing power more equitably across societal groups. However, in many cases, the outcome has been greater complexity, which has acted to create a different sort

of democratic deficit – a shift in the locus of the power base without corresponding improvement in the responsibility with which that power is exercised. The governance experiment of the past 20 years - involving a more bottom-up, stakeholder-led approach to risk management (Lyall and Tait, 2005), as applied to innovation in the life sciences - has not delivered greater consensus in decision-making: this is, as we argue above, a generally unrealistic and unattainable goal.

Stakeholder engagement practices that could lead to more democratic outcomes in the context of polarized and ideologically motivated opinions (Sunstein, 2009) are still unusual. We need clearer strategic thinking on how to implement a governance approach under these circumstances that encourages equitable dialogue across all societal groups, including scientists, industry, regulators, NGOs and citizens.

Research on governance-related issues in life sciences has identified an 'appropriate' approach as one that is enabling of innovation, minimises risk to people and the environment, and balances the interests and values of relevant stakeholders (Tait 2012). Achieving this balance requires a willingness to engage with the notion of tentative governance, and to be adaptive and willing to rethink and refine the basis on which we engage the full spectrum of stakeholders in these policy debates as our knowledge expands.

6 Conclusions

Governance is a highly problematic term when applied to innovation; often used indiscriminately and with various prefatory adjectives that tend to move us away from the original, more focused view of participative, network-based policy-making. As others have noted, the 'openness of the concept of governance…is both a strength and a weakness for the development of this body of theory' and there remains a 'good deal of skepticism about the general applicability of the concept' (Peters, 2014). To a certain degree, we share this scepticism when discussing the concept of 'tentative governance'.

As governance reaches a new level of maturity we could usefully revisit some of the debates about the role of deliberative democracy (e.g. Rayner, 2003; 2007) in order to be more constructive in our democratic engagement. This implies a dynamic continuum of relationships between science and society which must allow the policy and the politics back in to participation. A more interdisciplinary approach is required which learns from the political scientists' experience of governance theory where scholars increasingly believe that the 'high tide' of network governance may have passed (Davies, 2011, p.4).

If governance is 'tentative' when it is designed or evolves in response to a particularly dynamic process to manage interdependencies and contingencies, then, ultimately, there are improvements to be made in engagement processes and in the appropriate involvement of the social sciences. Within STS we have witnessed and, in many cases, facilitated the trajectory from deficit model to public engagement to upstream engagement. What we have learned is that a governance approach enlarges the political vision and the constellations of actors involved in policy making but it is not a panacea for the complexities of the modern policy world: intensely political decisions remain and must be taken by elected decision-makers. We also know that participation and decision-making take place at different levels and this leads to a significant governance gap. If there is to be a second generation of governance for the life sciences, it needs to make a mature assessment of the limitations of participation where consensus may not be possible or even desirable.

Kuhlmann et al. (this issue) suggest that 'tentative governance' serves as a heuristic to investigate whether a mode of governance is capable of reflexivity and they propose that EST governance increasingly searches and applies new approaches to cope with the problems of uncertainty. If governance in practice is to explicitly take into account the 'tentativeness' of the endeavour then we must strive to bring the three key elements – scientific evidence, public opinion and politics – into a better balance by adopting some new rules of engagement if we are to achieve a nuanced and serviceable understanding of

tentative governance within the context of policy making for the life sciences. Beyond this, as we argue above, while tentativeness is a useful attribute at the more upstream stages of development of an innovation, governance needs to become more adaptive and less tentative as it moves to more downstream stages of development.

If it is to resolve some of the still-extant dilemmas in the life sciences, a tentative governance approach needs to be equitably sceptical in appraising the evidence brought to the table by all interested parties (including companies and NGOs); it needs to be equitable in its involvement of all stakeholders in engagement initiatives; and it needs to be equitable in the way in which it acknowledges risks and opportunities (Tait *et* al., 2018). Ultimately, however, there may be no substitute for good judgement on the part of policy decision makers and supporting that process is a key potential contribution from social science research.

If we are to move beyond the limits to governance and develop a more critical understanding of its application in specific policy areas then we must better address the notion of 'balance' which is an aspect of governance that has been under-emphasised to date. As Kuhlmann et al. (this issue) note, many of the papers in this special section show that 'tentative governance involves a balancing between creating flexibility and stability, opening and closing options, and more or less tentative forms'. We share this view and we also recognise the hybrid nature of many governance approaches and share common ground with the Editors' concept of 'tentative governance' as it seeks to 'capture actors' attempts at creating spaces for probing and learning'.

Clearly, in an area as complex as the life sciences, governance and government approaches must be intertwined, with the hard core of government increasingly wrapped with a soft, outer layer of governance. Some of our suggestions for new rules of engagement may take us a step back towards previous government approaches that required separation of factual evidence as a basis for policy decisions from the political process of dealing with conflicting interests and values. In order to move beyond the limits to governance, we may be able to

use the heuristic device offered by tentative governance as a step towards developing and adopting new rules of engagement. However, we favour the adaptive governance approach over this proposed tentative concept, valuing the former's focus on progression and improvement. If it is to achieve sufficient traction, the 'tentative governance' approach needs to move beyond its neutral stance 'with regards to adaptation or improvement, learning or sheer experimentation' (Kuhlmann et al. this issue) in order to cope more effectively with the problems of uncertainty in areas such as the life sciences.

Acknowledgements

We would like to acknowledge the contribution of Dr John Purves, formerly European Medicines Agency, for information related to the development of the European Advanced Therapy Medicinal Product (ATMP) Regulation. This research has been supported by the UK Economic and Social Research Council (ESRC grants RES 145-28-1004 and RES-145-28-0002). We are grateful to the two anonymous referees for their comments on an earlier version of this paper.

7 References

Academy of Medical Sciences (2011), A new pathway for the regulation and governance of health research (London: Academy of Medical Sciences)

Anon (2010), Editorial – Talk no substitute for strategy, Research Fortnight, 17 November 2010.

Anon (2004), Editorial – Going public, Nature 431: 883.

Barnett, N. (2011), Local Government at the Nexus?, Local Government Studies, 37/3: 275-290

Barry, A. (2001), Political Machines: Governing a Technological Society (London and New York: The Athlone Press).

Bevir, M. and Rhodes, R.A.W (2010) The state as cultural practice (Oxford: OUP)

Bevir, M. and Rhodes, R.A.W. (2003). Interpreting British Governance, London, Routledge.

Börzel, T.A. (1998). Organizing Babylon - on the Different Conceptions of Policy Networks, Public Administration, 76 (Summer): 253-273.

Bodmer, W. (1985), The public understanding of science: report of the Royal Society's ad hoc group (London: The Royal Society).

Bruce, E. A. (2011), The textures of controversy: values and interests in disputes around genomics, PhD Thesis, (Milton Keynes: Open University)

Buyx, A. and Tait, J. (2011) Ethical Framework for Biofuels. Science, 332, 29 April, 2011, 540-541.

Calvert, J. and Martin, P. (2009), The role of social scientists in synthetic biology, EMBO reports, 10/3:201-204.

Collins, H. (2009) We cannot live by scepticism alone. Nature, 458, 30-31.

Davies, J. S. (2011), Challenging governance theory. From networks to hegemony (Bristol: Policy Press).

Escobar, O. (2011), Public Dialogue and Deliberation. A communication perspective for public engagement practitioners (Edinburgh Beltane Beacon for Public Engagement, University of Edinburgh).

Fagerberg, J., Landström, H. and Martin, B. R. (2012), Exploring the emerging knowledge base of 'the knowledge society', Research Policy, 41: 1121– 1131.

Felt, U. and Fochler, M. (2008), The bottom-up meanings of the concept of public participation in science and technology, Science and Public Policy, 35(7):489–499.

Greenaway, J., Salter, B. and Hart, S. (2007), How policy networks can damage democratic health: a case study in the government of governance, Public Administration, 85:3, 717-738.

Hagendijk, J. and Irwin, A. (2006), Public Deliberation and Governance: Engaging with Science and Technology in Contemporary Europe, Minerva, 44:167-184.

House of Lords (2000), Science and Society (London: Her Majesty's Stationery Office).

Irwin, A., Elgaard Jensen, T. and Jones, K. E. (2013), The good, the bad and the perfect: Criticizing engagement practice Social Studies of Science, 43: 118-135.

Irwin, A. (2006) The Politics of Talk: Coming to Terms with the 'New' Scientific Governance, Social Studies of Science 36/2:299–320.

Kaye, J. et al. (2012), ELSI 2.0 for Genomics and Society, Science (11 May 2012), 336/6082:673-674

Kooiman, J. (1993). Modern Governance. New Government-Society Interactions (London: Sage).

Laurie, G., Bruce, A. and Lyall, C. (2009), The Roles of Values and Interests in the Governance of the Life Sciences: Learning Lessons from the 'Ethics+' Approach of UK

Biobank in Lyall et al. (eds.) (2009), The Limits to Governance. The Challenge of Policy-making for the New Life Sciences (Aldershot: Ashgate)

Lofland, J. and Lofland, L. H. (1995), Starting Where You Are (Belmont CA: Wadsworth)

Lyall C. and Tait J. (eds.) (2005), New Modes of Governance: Developing an Integrated Policy Approach to Science, Technology, Risk and the Environment (Aldershot: Ashgate).

Lyall, C., Papiaoannou, T. and Smith, J. (eds.) (2009a),The Limits to Governance. The Challenge of Policy-making for the New Life Sciences (Aldershot: Ashgate)

Lyall, C., Papiaoannou, T. and Smith, J. (2009b), Governance in Action in the Life Sciences: Some Lessons for Policy in Lyall et al. (2009a)(eds.), The Limits to Governance. The Challenge of Policy-making for the New Life Sciences (Aldershot: Ashgate).

Lyall, C. (2007), Governing Genomics: New Governance Tools for New Technologies?, Technology Analysis and Strategic Management, 19/3:365-382.

Mothe, J.d.l. (2001). Knowledge, Politics and Governance in Mothe, J.d.l. (ed.) Science, Technology and Governance (London: Continuum).

Marazzi, M. (2013), Asking a butcher to bake bread makes no sense - so why ask EMA to approve medical devices? Blog, 25 February 2013 MedTech Europe http://www.medtechviews.eu/article/asking-butcher-bake-bread-makes-no-sense-so-why-ask-ema-approve-medical-devices (accessed 10/12/18)

Marinetto, M. (2003). Governing beyond the Centre: A Critique of the Anglo-Governance School, Political Studies, 51(3): 592-608.

Mayntz, R. (2003), New challenges to governance theory in Bang, H. (ed.), Governance as social and political communication (Manchester, New York: Manchester University Press).

Mittra, J., Tait, J., Mastroeni, M., Turner, M., Mountford, J., Bruce, K., (2015) Identifying Viable Regulatory and Innovation Pathways for Regenerative Medicine: A Case Study of Cultured Red Blood Cells, *New Biotechnology*, 32/1: 180-190

Mouffe, C. (2000), The Democratic Paradox (London: Verso).

Nowotny, H. and Testa, G. (2010), Naked Genes. Reinventing the human in the molecular age (Cambridge, MA and London: MIT Press).

Nuffield Council on Bioethics (2011), Biofuels: Ethical Issues (London: Nuffield Council on Bioethics)

Nuffield Council on Bioethics (2012), Emerging Biotechnologies: technology, choice and the public good. (London: Nuffield Council on Bioethics)

Omidvar, O., de Grijs, M., Castle, D., Mittra, J., Rosiello, A. and Tait, J. (2014) *Regenerative Medicine: Business Models, Venture Capital and the Funding Gap.* Report to ESRC and InnovateUK, 30th Oct, 2014. http://www.innogen.ac.uk/downloads/RegenerativeMedicine-BusinessModels-VentureCapital-and-theFundingGap-Oct14.pdf (accessed 13/12/18)

Peters, B. G. (2014), Is governance for everybody? (Introduction to special issue) Policy and Society, 33/4: 301–306

Pielke Jr., R. (2007), The Honest Broker (Cambridge: Cambridge University Press).

Pierre, J. and Peters, B. G. (2000), Governance, Politics and the State (Basingstoke: Macmillan).

Rayner, S. (2007), The rise of risk and the decline of politics, Environmental Hazards 7:165–172

Rayner, S. (2003), Democracy in the age of assessment: reflections on the roles of expertise and democracy in public-sector decision making, Science and Public Policy, 30/3:163–170.

Rehmann-Sutter, C. (2012) “Second Generation Governance for Second Generation GM” in Howlett, M. and Laycock, D. (eds) *Regulating Next Generation Agri-Food Biotechnologies. Lessons from European, North American and Asian Experiences* (London: Routledge)

Rhodes, R.A.W. (2007), Understanding Governance: Ten Years On, Organization Studies 28:08, 1234-1264.

Rip, A. (2009), Futures of ELSA, EMBO reports, 10/7:666-670.

Rose, N. (1999), Powers of Freedom: Reframing Political Thought (Cambridge, UK: Cambridge University Press).

Sarewitz, D. (2010), Politicize me, Nature, 467 2 September p.26.

Sciencewise (2010), International Comparison of Public Dialogue on Science and Technology (London: BIS).

Sorensen, E. and Torfing, J. (2009), Making governance networks effective and democratic thorough metagovernance, Public Administration, 87/2: 234-258.

Stilgoe, J., Lock, S. J. and Wilsdon, J. (2014), Why should we promote public engagement with science? Introduction to Special Issue: Public Engagement in Science, Public Understanding of Science, 23/1: 4-15.

Stirling, A. (2008), Opening Up and Closing Down. Power, Participation and Pluralism in the Social Appraisal of Technology’, Science, Technology and Human Values, 33/2:262-294.

Stirling, A. (2014) Making choices in the face of uncertainty: strengthening innovation democracy. In Annual Report of the Government Chief Scientific Adviser, 2014. *Innovation:*

Managing Risk not Avoiding It. Evidence and Case Studies, pp 49-62 (https://www.gov.uk/government/publications/innovation-managing-risk-not-avoiding-it) (accessed 13/12/18)

Stoker, G. (2006), Why Politics Matters: Making Democracy Work. (Basingstoke and New York: Palgrave, Macmillan).

Stoker, G. (1998). Governance as theory: five propositions, International Social Science Journal, 50(155): 17-28.

Sunstein C.R. (2009), Going to Extremes: How Like Minds Unite and Divide (Oxford, UK: Oxford University Press)

Tait, J., Banda, G. and Watkins, A. (2018) Proportionate and Adaptive Governance of Innovative Technologies (PAGIT): Case Study: Responsible Governance of Innovative Technologies, Final Report. Innogen Institute Report to the British Standards Institution. https://www.innogen.ac.uk/reports/1302 (accessed 13/12/18)

Tait, J., Banda, G. and Watkins, A. (2017) *Proportionate and Adaptive Governance of Innovative Technologies: a framework to guide policy and regulatory decision making.* Innogen Institute Report to the British Standards Institution. https://www.innogen.ac.uk/reports/1222 (accessed 10/12/18)

Tait, J. (2017) From Responsible Research to Responsible Innovation: Challenges in Implementation. Engineering Biology, 1(1): 7-11.

Tait, J. and Banda, G. (2016) *Proportionate and Adaptive Governance of Innovative Technologies: the role of regulations, guidelines and standards. Full Report to British Standards Institution.* (http://www.bsigroup.com/research-pagit-uk) (accessed 10/12/18)

Tait, J. (2014), Bringing it all Together, Chapter 11 in Annual Report of the Government Chief Scientific Adviser 2014. Innovation: Managing Risk, Not Avoiding It. Evidence and Case Studies (London: The Government Office for Science)

Tait, J. (2102), Appropriate Governance of the Life Sciences – 11: Governing Synthetic Biology, https://www.innogen.ac.uk/downloads/AGLS-11-Governing-Synthetic-Biology.pdf (accessed 13/12/18)

Tait, J. and Barker, G. (2011), Global food security and the governance of modern biotechnologies, EMBO reports, 12: 763 - 768

Tait, J. and Chataway, J. (2010) Appropriate Governance of the Life Sciences – 9: Pros and Cons of the Precautionary Principle (PP): European Experience with the regulation of GM Crops, Innogen Policy Brief, https://www.innogen.ac.uk/downloads/AGLS-09-Pros-and-cons-of-Precautionary-Principle.pdf (accessed 13/12/18)

Tait, J. (2009a), Foreword in Lyall et al. (eds.), The Limits to Governance. The Challenge of Policy-making for the New Life Sciences (Aldershot: Ashgate).

Tait, J. (2009b), Upstream Engagement and the Governance of Science: the shadow of the GM crops experience in Europe, EMBO Reports. Vol 10, Special Issue, pp 18-22.

Tait, J., Chataway, J. and Wield, D., (2007a), Appropriate Governance of the Life Sciences – 2: The Case for Smart Regulation, Innogen Policy Brief, https://www.innogen.ac.uk/downloads/AGLS-02-The-Case-for-Smart-Regulation.pdf (accessed 13/12/18)

Tait, J., Bruce, A., Chataway, J. and Wield, D., (2007b), Appropriate Governance of the Life Sciences – 3: Regulating GM Crops: lessons for next generation technologies, Innogen Policy Brief, https://www.innogen.ac.uk/downloads/AGLS-03-Regulating-GM-Crops.pdf (accessed 13/12/18)

Tait, J. (2007a) Systemic Interactions in Life Science Innovation. *Technology Analysis and Strategic Management, 19(3),* 257-277, May 2007.

Tait, J. (2007b), Risk Governance of Genetically Modified Crops: European and American Perspectives in O. Renn and K. Walker (eds.), Global Risk Governance: Concept and Practice Using the IRGC Framework. Dordrecht, (NL: Springer Science and Business Media); pp 133-153.

Tait, J., Chataway, J., Lyall, C. and Wield, D. (2006), Governance, Policy and Industry Strategies: Pharmaceuticals and Agro-biotechnology in Mazzucato, M. and Dosi, G. (eds.) Innovation, Growth and Market Structure in High-tech Industries: The Case of Biotech-Pharmaceuticals. (Cambridge: Cambridge University Press).

Tait, J. (2001) More Faust than Frankenstein: the European Debate about Risk Regulation for Genetically Modified Crops. Journal of Risk Research, 4(2), 175-189.

Thompson, G.F. (2003). Between Hierarchies and Markets. The Logic and Limits of Network Forms of Organisation (Oxford: Oxford University Press).

Verweij, M., Douglas, M., Ellis, R., Engel, C., Hendriks, F., Lohmann, S., Ney, S, Rayner, S., Thompson M. 2006. Clumsy solutions for a complex world: the case of climate change. Public Administration 84: (4): 817-843.

Wagner, W. (2005), The Perils of Relying on Interested Parties to Evaluate Science, American Journal of Public Health, 95/7S: S99-S106.

Walls, J., Riordan, T., Horlick-Jones, T. and Niewohner, J. (2005), The meta-governance of risk and new technologies: GM crops and mobile telephones, Journal of Risk Research 8 (7-8): 635-661.

Walport, M. and Craig, C. (2014), Annual Report of the Government Chief Scientific Adviser 2014. Innovation: Managing Risk, Not Avoiding It (London: The Government Office for Science)

Webster, A. (2007), Crossing Boundaries. Social Science in the Policy Room, Science, Technology and Human Values, 32/4:458-477.

Williams. R. (2006), Compressed foresight and narrative bias: pitfalls in assessing high technology futures, Science as Culture, 15: 327-348.

Wilsdon, J. and Willis, R. (2004), See-through science – why public engagement needs to move upstream (London, UK: Demos)