Synthesise This: Integrating Innovation Governance and EU Regulation of Synthetic Biology

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Responsible innovation (RI) is an innovation governance framework, developed by Science and Technology Studies (STS), which seeks to transform innovation processes. While legal academia has derived valuable insights from STS for regulating technology, it has largely not considered the implications of developments on RI for the law. This article aims to address this using EU governance of synthetic biology (synbio) as a case study. It highlights how the existing regulatory framework struggles to accommodate the diverse issues synbio raises and explores hybrid approaches using soft mechanisms to enhance the effectiveness of hard law in governing technology. Considering the entire 'governance continuum' as a whole, the article argues firstly that while such hybrid approaches offer potential for implementing RI, they are currently limited, and secondly that for RI to transform innovation processes, hard law must also adapt. The article suggests finally that RI itself offers guidance for addressing those two needs.

INTRODUCTION

Governing the emergence of new, often controversial technology is complex and inevitably requires insight from different disciplines. Legal academia and social science, particularly science and technology studies (STS), have both made significant contributions, expanding our understanding of public attitudes to risk, science-society relations and the institutions, procedures and expertise associated with risk-based regulation. While different disciplinary lenses naturally interrogate different phenomena, maintaining porous disciplinary boundaries can enrich thinking, knowing and understanding within disciplines.[1]

Both legal academia and STS often pursue improvement in technology governance and frequently overlap. STS has engaged with the law.[2] Legal academia, especially in environmental law, has used STS research on scientific risk assessment and the public understanding of science to evaluate laws regulating technology and risk,[3] highlighting the limitations of regimes governing, for example,

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[1] M. Lee et al., 'Crossing Disciplines in Planning: A Renewable Energy Case Study' in *Perspectives on Environmental Law Scholarship*, ed. O. Pedersen (2018); I.D. Willock, 'Getting on with Sociologists' (1974) 1 *Brit. J. of Law and Society* 3, at 5–6.

[2] For example, S. Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (2007); S. Jasanoff, *Science at the Bar: Law, Science, and Technology in America* (1997); D. Winickoff et al., 'Adjudicating the GM Food Wars: Science, Risk, and Democracy in World Trade Law' (2005) 30 *Yale J. of International Law* 81.

[3] For example, E. Fisher, *Risk: Regulation and Administrative Constitutionalism* (2007) ch. 1; E. Fisher, 'Risk and Environmental Law: A Beginner's Guide' in *Environmental Law for Sustainability: A Reader*, eds. B. Richardson and S. Wood (2006); L. Bennett Moses, 'Regulating in the Face of Sociotechnical Change' in *The Oxford Handbook of Law, Regulation and Technology*, eds. R. Brownsword et al. (2017).

biotechnology and nanotechnology, which rely primarily on risk assessment.[4] More recent trends in STS have shifted from criticism of risk assessment as an evidence base in 'downstream' pre-market authorisation procedures for finished technological products. Instead, attention has turned to 'upstream' innovation processes such as the early stages of R&D, defining research agendas and the allocation of funding.[5] In short, much STS scholarship focuses now on 'innovation governance'.

While these developments may have implications for the law, they have largely escaped the attention of legal academics.[6] There is therefore a lack of legal academic analysis of those potential implications including whether, and if so how, the law should respond. In research strategy terms therefore, this article aims to maintain and further connections between legal academia concerning technology regulation and current STS research on innovation governance by considering recent developments in STS and their potential future interaction with the law. This article is not about interdisciplinary methodology. Rather, it is concerned with viewing the governance and regulation of emerging technologies holistically and increasing coordination between the processes and frameworks governing the various stages of technology emergence. This requires transcending disciplinary boundaries to consider, together, governance processes or frameworks traditionally examined within the discrete provinces of STS and legal academia.[7] To do this, I take the EU's regulation of synthetic biology (synbio) – a controversial, emerging area of research and innovation – as a case study to highlight the deficiencies of narrow risk-based regimes for regulating emerging technologies. Soft mechanisms, in combination with hard regulation, are key to governing innovation, including synbio.[8] Building on a discussion of previous experience with hybrid approaches to governing emerging technologies, I explore how such approaches may limit the ambitions of the new developments in innovation governance and potential for more fruitful interaction between soft governance and traditional legal regulation.

My focus is the EU. I begin by discussing developments in STS regarding Responsible Innovation (RI) – an ambitious innovation governance framework – and the tensions it creates with existing EU innovation policy. In section II, I introduce synbio. I explore its potential risks and benefits and how RI might work in this field. In section III, I discuss the Contained Use Directive (CUD)[9] and the Deliberate Release Directive (DRD),[10] a regime which exemplifies the limitations of risk-based regulation. Both apply to synbio, though they were originally designed to regulate genetically modified organisms (GMOs) and predate much policy and research on RI. However, the novel ambition of, and concerns raised by, synbio, plus growing pressure to open up broader questions around research and innovation represent an opportunity to re-assess the regime's potential to accommodate such concerns and

[4] See contributions to M. Everson and E. Vos (eds.), *Uncertain Risks Regulated* (2009); M. Lee, 'Beyond Safety? The Broadening Scope of Risk Regulation' (2009) 62 *Current Legal Problems* 242; M. Lee, *EU Regulation of GMOs: Law and Decision Making for a New Technology* (2008) ch. 2.

[5] J. Wilsdon and R. Willis, *See-through Science: Why Public Engagement Needs to Move Upstream* (2004).

[6] Exceptions include R.G. Lee and J. Petts, 'Adaptive Governance for Responsible Innovation' in *Responsible Innovation: Managing the Responsible Emergence of Science and Innovation in Society*, eds. R. Owen et al. (2013); R.G. Lee, 'Look at Mother Nature on the Run in the 21st Century: Responsibility, Research and Innovation' (2012) 1 *Transnational Environmental Law* 105.

[7] Fragmentation in the processes and institutions governing technological innovation has been observed elsewhere, for example R. Owen and N. Goldberg, 'Responsible Innovation: A Pilot Study with the U.K. Engineering and Physical Sciences Research Council' (2010) 30 *Risk Analysis* 1699, at 1700; E. Fisher et al., 'Midstream Modulation of Technology: Governance From Within' (2006) 26 *Bull. of Science, Technology & Society* 485, at 486.

[8] See, for example, the SYNENERGENE project, <https://www.synenergene.eu>.

[9] Directive 2009/41/EC on the contained use of GM micro-organisms [2009] OJ L125/50.

[10] Directive 2001/18/EC on the deliberate release into the environment of GM organisms [2001] OJ L106/1.

pressures. I argue that, given the regime's traditional focus on facilitating trade and ensuring safety, which reflect long-standing policy assumptions about innovation, potential is limited.

Soft law currently represents the most likely route for implementing RI[11] and soft mechanisms already exist. In section IV, I discuss previous experience with using soft mechanisms as part of a hybrid approach to governing technology. I argue that, while soft mechanisms have significant potential, they exhibit profound weaknesses which need addressing to enhance the effectiveness of hybrid approaches. In section V, I turn to using hybrid approaches to implement RI specifically. I argue firstly that such approaches, as currently employed, are insufficient to support RI's ambitions to transform innovation processes and secondly that realising these transformative ambitions entails addressing the entire 'governance continuum' including how traditional legal regulation may also require adaptation. I argue, finally, that RI itself may offer guidance for addressing the various problems identified. Section VI concludes.

I. RESPONSIBLE INNOVATION

STS research has long highlighted the deficiencies of scientific risk assessment as the primary tool for regulating emerging technologies[12] as well as the failures of governance by market choice to prevent innovation's negative externalities.[13] As discussed, recent attention has shifted to opening up upstream research and innovation systems, recognising the need to debate not only the implications of science and innovation but also their processes and trajectories.[14] This development is a response to the transformative potential of science and technology for society and the frequent failure of risk assessment to predict societal impacts.[15] Responsible Innovation (RI) grows out of this fertile STS research[16] and aspires to transform institutions on risk, ethics and innovation from expert-domination to open deliberation.[17] The terms 'responsible innovation' and 'responsible research and innovation' (RRI) are often used interchangeably. While early formulations of RI and RRI shared various characteristics and still exhibit overlaps, they increasingly diverge and refer to different discourses. RRI is an EU policy-driven discourse; RI originates largely in academia.[18] RI requires anticipatory governance, including participatory debate on the world we are creating with innovation.[19] It departs from mechanisms of retrospective liability and accountability, including 'evidence-based' risk regulation (see section III),[20] codes of conduct and ethical review;[21] the traditional framework for

[11] Lee and Petts, op. cit., n. 6.
[12] For a detailed summary, see EGSG, *Taking European Knowledge Society Seriously* (2007). See also B. Wynne, 'Uncertainty and Environmental Learning: Reconceiving Science and Policy in the Preventive Paradigm' (1992) 2 *Global Environmental Change* 111; B. Wynne, 'Understanding Public Risk Perception' in *Risk Analysis in Nuclear Waste Management*, eds. A. Saltelli et al. (1989); Jasanoff, op. cit. (2007), n. 2.
[13] R. Owen et al., 'A Framework for Responsible Innovation' in Owen et al., op. cit., n. 6, pp. 27-28.
[14] Ž. Ozoliņa et al., *Global Governance of Science* (2009) 15.
[15] J. Stilgoe et al., 'Developing a Framework for Responsible Innovation' (2013) 42 *Research Policy* 1568, at 1569.
[16] M. van Oudheusden, 'Where Are the Politics in Responsible Innovation? European Governance, Technology Assessments, and Beyond' (2014) 1 *J. of Responsible Innovation* 67, at 71.
[17] C. Wilkinson et al., *Ex-Post Evaluation of Science in Society in FP7: Final Report* (2016) 41.
[18] R. Owen and M. Pansera, 'Responsible Innovation and Responsible Research and Innovation' in *Handbook on Science and Public Policy*, eds. D. Simon et al. (2019).
[19] Lee, op. cit., n. 6, pp. 108–109.
[20] Stilgoe et al., op. cit., n. 15, pp. 1569–1570.
[21] Owen et al., op. cit., n. 13, p. 30.

ensuring responsibility in scientific research, which struggles to accommodate the complexity and uncertainty of technological innovation and wider social, economic, ethical concerns and impacts.[22]

While recognising the weaknesses of traditional regulation, RI also acknowledges Collingridge's dilemma of control[23] which argues that neither upstream nor downstream intervention alone may adequately control technology.[24] Upstream innovation governance has limits relating to, for example, scale, speed of innovation and the timing and purpose of engagement,[25] particularly given the degree of abstraction and generalisation necessary in discussion.[26] Innovation governance and regulation exist on a continuum: each opportunity for intervention, equally valuable yet insufficient, requires a bespoke governance toolkit 'responsive to changing societal views and expectations about technologies'.[27] They should, furthermore, complement and enhance each other's effectiveness, as discussed in sections IV and V.

RI attempts to address this dilemma. It recognises that risk, as originating in technological and social systems,[28] demands responsibility shared among scientists, funders, innovators and others and reimagines responsibility in (environmental) regulation or governance as future-orientated care and 'responsiveness'.[29] It acknowledges that innovation raises questions which are trans-scientific, extending beyond issues of risk to fundamental questions about direction, application and control.[30] It encourages scientists to reflect on the broader ethical and moral dimensions of their research.[31] While responsibility sharing may not remove risk, it may 'enhance anticipatory governance by conferring greater legitimacy'.[32] RI may be defined as:

> *[A] transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society).*[33]

Broadly speaking, RI aims to promote collectively defined goals, through engagement and mutual learning between scientists and stakeholders, including publics. It encompasses four dimensions: anticipation, for example considering the likely consequences of innovation; reflexivity, involving actors reflecting on their own commitments and assumptions; inclusion, referring to public

[22] id., pp. 32–33; L. Pellizzoni, 'Responsibility and Environmental Governance' (2004) 13 *Environmental Politics* 541, at 544–557.
[23] Owen and Pansera, op. cit., n. 18, p. 30.
[24] D. Collingridge, *The Social Control of Technology* (1980) 17–20.
[25] Lee and Petts, op. cit., n. 6, pp. 158–160.
[26] id.; M. Lee, 'Public Participation, Procedure, and Democratic Deficit in EC Environmental Law' (2003) 3 *The Yearbook of European Environmental Law* 193, at 213.
[27] Lee and Petts, op. cit., n. 6, p. 158.
[28] T. Hellström, 'Systemic Innovation and Risk: Technology Assessment and the Challenge of Responsible Innovation' (2003) 25 *Technology in Society* 369, at 369–370.
[29] Stilgoe et al., op. cit., n. 15, p. 1569.
[30] Lee and Petts, op. cit., n. 6, p. 144.
[31] K. Asante et al., 'Governance of New Product Development and Perceptions of Responsible Innovation in the Financial Sector: Insights from an Ethnographic Case Study' (2014) 1(1) *J. of Responsible Innovation* 9, at 14; A. Genus and A. Stirling, 'Collingridge and the Dilemma of Control: Towards Responsible and Accountable Innovation' (2018) 47 *Research Policy* 61, at 63.
[32] Lee, op. cit., n. 6, p. 110.
[33] R. von Schomberg, 'Prospects for Technology Assessment in a Framework of Responsible Research and Innovation' in *Technikfolgen abschätzen lehren*, eds. M. Dusseldorp and R. Beecroft (2012) 9.

deliberation and debate about innovation; and responsiveness, meaning that the direction of innovation should respond to stakeholder and public values.[34]

In practice, RI embraces myriad established procedures, techniques and tools to implement one or more dimensions. For example, technology assessment (TA) and technology foresight may help anticipate positive and negative impacts of research and innovation, or identify 'socially desirable' products.[35] When integrated into R&D processes, these insights enhance reflexivity and responsiveness to societal concerns. 'Stage gating' manages R&D processes using decision points, which may incorporate RI dimensions prompting researchers to anticipate, reflect and deliberate on the purposes, potential impacts and outcomes of their research and respond appropriately.[36] Funders may require applicants to submit 'risk registers' encouraging early anticipation, reflection on and responsiveness to the wider implications of their research.[37] R&D agendas may also be governed through 'midstream modulation', prompting reflection on and change in, *inter alia*, strategic decision-making,[38] when trajectories may be influenced 'more concretely than upstream and more flexibly than downstream'.[39]

The above approaches should generally be conducted inclusively. The inclusion dimension of RI establishes space for broad public deliberation and dialogue in the upstream governance of innovation.[40] Downstream, pre-market public engagement on the risks of a developed technology is often criticised for serving token or instrumental purposes, such as cultivating public trust or 'acceptance' of the technology and its risks, or occurring too late to influence significant decisions or applications.[41] By contrast, the benefits of early engagement include potential to imagine and debate future trajectories and impacts of innovation, influence crucial decisions and, ideally, avoid the polarisation and controversy often experienced downstream.[42] Opening up funding priorities to public discussion can reveal preferences for particular lines of research, which may spur more socially attuned decision-making.[43] Experiments in upstream engagement suggest that it may help shape innovation trajectories or increase the public value of technologies.[44] It may engender reflexivity by confronting researchers and policy-makers with alternative value-framings challenging 'assumptions of scientific amorality and agnosticism'.[45] It should be ongoing[46] and demand not just involvement of diverse groups but that the topics under discussion 'reflect the full range of aspirations and concerns'

[34] Stilgoe et al., op. cit., n. 15.
[35] R. von Schomberg, 'A Vision of Responsible Research and Innovation' in Owen et al., op. cit., n. 6, pp. 64-65.
[36] Owen et al., op. cit., n. 13, pp. 42–43.
[37] Owen and Goldberg, op. cit., n. 7.
[38] E. Fisher and A. Rip, 'Responsible Innovation: Multi-Level Dynamics and Soft Intervention Practices', in Owen et al., op. cit., n. 6, pp. 173–175.
[39] Fisher et al., op. cit., n. 7, pp. 491–492.
[40] Stilgoe et al., op. cit., n. 15, pp. 1571–1572.
[41] N. Pidgeon and T. Rogers-Hayden, 'Opening up Nanotechnology Dialogue with the Publics: Risk Communication or "Upstream Engagement"?' (2007) 9 *Health, Risk & Society* 191, at 194.
[42] id.; Wilsdon and Willis, op. cit., n. 5.
[43] R. Jones, 'When It Pays to Ask the Public' (2008) 3 *Nature Nanotechnology* 578.
[44] J. Stilgoe, *Nanodialogues: Experiments in Public Engagement with Science* (2007).
[45] Stilgoe et al., op. cit., n. 15, p. 1571.
[46] J. Wilsdon et al., *The Public Value of Science: Or How to Ensure That Science Really Matters* (2005) 38–40.

of the participants, including the purposes and motivations of the science and innovation[47] and the way the dialogue is framed, for example the breadth of questions and range of alternatives.[48]

Rationales for public engagement or deliberation, generally, include improved decisions[49] and bolstering democracy.[50] However, beneficial outcomes for institutional learning remain contingent on framings of the issues debated, the construction of participants and audiences and assumptions underlying the exercise.[51] Upstream engagement too may be used instrumentally, reinforcing pre-determined policy commitments, or operate as reductively as expert analysis itself,[52] instead of pursuing genuine, substantive change.[53] It may be employed as risk management[54] or in hopes of dispelling controversy.[55] Even the stream metaphor suggests unidirectional, deterministic technological progress,[56] a model ill-fitting the realities of research and innovation.[57]

RI is more than a collection of established norms and approaches and represents a coherent framework for governing innovation processes. Owen et al. identify a distinguishing, emergent feature of particular interest when considering implications for regulation. Innovation policy to date has been dominated by framings which promote innovation as key to market creation, exploitation, economic growth and competitiveness.[58] EU innovation policy follows suit, championing all innovation as neutral and directionless while automatically delivering jobs and economic growth. Innovation is regarded as inherently good and promoted as a goal in itself.[59] By contrast, RI emphasises science *for* society – that science and innovation should address societal challenges and pursue the 'right impacts', as defined through open and inclusive deliberation, while acknowledging that these are contested and different visions may be incompatible.[60] RI thus seeks to steer innovation towards socially desirable outcomes and justify innovation 'in terms of broadly shared public values' and expectations.[61]

This ambition creates tensions with the above dominant (economic) policy expectations of innovation and disrupts the traditional division of moral labour in which responsibility for producing beneficial innovation leading to progress and controlling the impacts of such innovation are attributed respectively to scientists and the public sector, with the market responsible for distributing benefits.[62] As discussed in section III, these traditional expectations also underpin regulation which dominant

[47] R. Owen et al., 'Responsible Research and Innovation: From Science in Society to Science for Society, with Society' (2012) 39 *Science and Public Policy* 751, at 754.
[48] K. Sykes and P. Macnaghten, 'Responsible Innovation - Opening Up Dialogue and Debate' in Owen et al., op. cit., n. 6, p. 96.
[49] J. Parkins and R. Mitchell, 'Public Participation as Public Debate: A Deliberative Turn in Natural Resource Management' (2005) 18 *Society & Natural Resources* 529, at 531–533.
[50] M. Ahteensuu and H. Siipi, 'A Critical Assessment of Public Consultations on GMOs in the European Union' (2009) 18 *Environmental Values* 129, at 132–134.
[51] A. Irwin, 'Constructing the Scientific Citizen: Science and Democracy in the Biosciences' (2001) 10 *Public Understanding of Science* 1.
[52] A. Stirling, '"Opening Up" and "Closing Down": Power, Participation, and Pluralism in the Social Appraisal of Technology' (2008) 33 *Science, Technology & Human Values* 262.
[53] Stilgoe, op. cit., n. 44, p. 73.
[54] id., p. 18.
[55] Wilsdon et al., op. cit., n. 46, pp. 33–34.
[56] Stirling, op. cit., n. 52, p. 264.
[57] Fisher et al., op. cit., n. 7, p. 490.
[58] J. Schot and W.E. Steinmueller, 'Three Frames for Innovation Policy: R&D, Systems of Innovation and Transformative Change' (2018) 47(9) *Research Policy* 1554.
[59] von Schomberg, op. cit., n. 35, pp. 54, 58.
[60] Owen et al., op. cit., n. 47, pp. 754–755.
[61] R. von Schomberg, 'Why Responsible Innovation?' in *International Handbook on Responsible Innovation: A Global Resource*, eds. R. von Schomberg and J. Hankins (2019) 14, 16-19.
[62] Fisher and Rip, op. cit., n. 38, p. 178; Schot and Steinmueller, op. cit., n. 58, p. 1557.

framings conceive of as an 'add-on' to address the (often exclusively safety) impacts of innovation reinforcing the above division of labour.[63] RI has the capacity to 'disrupt existing institutional logics relating to research and innovation' and implies transforming relationships between science, technology, innovation and society and the responsibilities of scientists, innovators, markets and the state.[64]

The above tensions, however, may dilute RI's transformative potential.[65] Innovation may be superficially justified by reference to societal challenges. Such justifications leave existing innovation trajectories intact and risk instrumental use of RI to implement incumbent innovation pathways.[66] This may require a commitment to 'governing in the public interest' to counter unreflective use of RI by policy-makers for instrumental ends and a recognition that public concerns often relate to how science is governed as opposed, simply, to individual technologies in themselves.[67] RI urges, therefore, moving beyond the risks and economic benefits of individual technologies to address whole innovation process, including choices over which pathway to follow.[68] As such, RI involves and supports systemic transformation of our innovation systems including along the dimensions discussed above[69] and, even more ambitiously, the structure of our economy and society. This includes the way we regulate emerging technology and the potential contribution of regulation to the transformation sought,[70] discussed further below.

The EU and Member States have made progress, albeit limited, in implementing RI, or some shade of responsibility, through various soft instruments.[71] While the tools mentioned above (TA, stage gating etc.) aim to 'problematise and invite', these mechanisms offer soft prescriptions.[72] For example, the EU's *Nano Code* aims to foster a 'general culture of responsibility'[73] and the UK's *Responsible NanoCode* includes principles encouraging responsive engagement with stakeholders and consideration of wider social and ethical implications of nanotechnologies.[74] Various funding organisations have also adopted RI,[75] including the Engineering and Physical Sciences Research Council, which funds synbio research.[76] The British Standards Institute recently introduced guidance for companies wishing to innovate responsibly.[77] From 2013-2017, the EU ran SYNENERGENE, an action plan aiming to contribute to RRI/RI in synbio through multi-stakeholder dialogue over risks and benefits and collaborative shaping of research.[78] Further afield, in 2019, the OECD adopted a Recommendation on Responsible Innovation in Neurotechnology which encourages, *inter alia*, consideration of public values in the design phase of technology development and societal

[63] Schot and Steinmueller, id., pp. 1556-7, 1561.
[64] R. Owen et al., 'Organisational Institutionalisation of Responsible Innovation' (2021) 50 *Research Policy* 1, at 2.
[65] Some already detect this in the EU, S. de Saille, 'Innovating Innovation Policy: The Emergence of "Responsible Research and Innovation"' (2015) 2 *J. of Responsible Innovation* 152.
[66] Genus and Stirling, op. cit., n. 31, p. 62.
[67] P. Macnaghten and J. Chilvers, 'The Future of Science Governance: Publics, Policies, Practices' (2014) 32 *Environment and Planning C: Government and Policy* 530.
[68] Genus and Stirling, op. cit., n. 31, p. 62.
[69] Owen and Pansera, op. cit., n. 18, p. 27.
[70] Schot and Steinmueller, op. cit., n. 58, pp. 1563, 1565.
[71] Thanks to an anonymous peer reviewer for highlighting some of these.
[72] Fisher and Rip, op. cit., n. 38, p. 177.
[73] Commission Recommendation 2008/345/EC on a code of conduct for responsible nanosciences and nanotechnologies research [2008] OJ L116/48.
[74] Insight Investment et al., *Responsible Nano Code* (2008).
[75] Fisher and Rip, op. cit., n. 38, pp. 169-171.
[76] For more detail, see Owen et al., op. cit., n. 64.
[77] BSI, *PAS 440 Responsible Innovation – Guide* (2020).
[78] See <https://www.synenergene.eu/information/what-synenergene.html>

deliberation.[79] As discussed below, however, more is needed to harness the full potential of such soft instruments to further RI.

II. SYNTHETIC BIOLOGY: PROMISES AND RISKS

Synbio involves the application of engineering principles to biology.[80] It is 'the rational design and construction of new biological parts, devices and systems with predictable and reliable functional behaviour that do not exist in nature, and the re-design of existing, natural biological systems for basic research and useful purposes',[81] for example social or commercial benefit.[82] Much synbio resembles genetic modification (GM). What distinguishes it is arguably less its techniques and processes but its conceptual framework; its philosophy, assumptions and ambitions, complete with epic narratives about 'creating life',[83] eventually perhaps from non-living materials.[84] This article treats synbio as different to GM and uses the term 'synthetic organism' (SO) to acknowledge that approach, despite the fact that many SOs are technically 'genetically modified'.

Synbio promises multiple outputs and industrial applications including biosensors, biofuels, biomedicine, food ingredients and chemicals, improving nutrition, healthcare and decontaminating the environment.[85] Much of the research is contained and works with well-characterised micro-organisms and genetic material, although longer-term developments may produce SOs which differ fundamentally from naturally occurring organisms.[86] Concerns often relate to the release of poorly characterised new biological machines, their possible hazardous qualities and potential effects on the environment or human health, exacerbated by unpredictable multiplication rates.[87] Risks include horizontal transfer of synthetic genes to other organisms or the colonisation and take-over of natural microbial communities.[88]

Equally important are socio-economic and ethical implications, the correct approach to intellectual property (IP) rights in the processes and products of synbio and the distribution of risks and benefits. A bioeconomy which increases demand for biomass to process into industrial products could encourage land grab in the search for farmland to meet demand and destroy biodiversity at the expense of local communities,[89] or exacerbate problems with food security already associated with competition between biofuels and food.[90] Shifting from cultivated to synthetic medical products could, *inter alia*, concentrate power in western pharmaceutical companies by transferring production from developing countries,[91] threaten the livelihoods of small-scale farmers,[92] while IP frameworks

[79] OECD, *Recommendation of the Council on Responsible Innovation in Neurotechnology* (2019) <https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0457>

[80] EASAC, *Realising European Potential in Synthetic Biology: Scientific Opportunities and Good Governance* (2010) 5.

[81] K. Pauwels et al., 'Synthetic Biology: Latest Developments, Biosafety Considerations and Regulatory Challenges' (2012) D/2012/2505/46 3.

[82] EASAC, *Synthetic Biology: An Introduction* (2011) 4.

[83] See contributions to J. Boldt (ed.), *Synthetic Biology: Metaphors, Worldviews, Ethics, and Law* (2016).

[84] EASAC, op. cit., n. 82, p. 3.

[85] Commission, *Synthetic Biology: Applying Engineering to Biology* (2005) 13–17.

[86] Pauwels et al., op. cit., n. 81, p. 3.

[87] B. Giese et al., 'Promising Applications of Synthetic Biology - and How to Avoid Their Potential Pitfalls' in Boldt op. cit., n. 83, p. 198.

[88] V. de Lorenzo, 'Environmental Biosafety in the Age of Synthetic Biology: Do We Really Need a Radical New Approach?' (2010) 32 *BioEssays* 926, at 927.

[89] ETC Group, *The New Biomassters: Synthetic Biology and the Next Assault on Biodiversity and Livelihoods* (2010).

[90] ETC Group, *Extreme Genetic Engineering: An Introduction to Synthetic Biology* (2007) 28–31.

[91] id., pp. 40–42, 52–55.

[92] Science for Environment Policy, *Future Brief: Synthetic Biology and Biodiversity* (2016) 15.

may prevent developing countries accessing the benefits produced.[93] The implications of synbio for the relationship between man and nature, or the distinction between man and machine,[94] prompt ethical concerns. Finally, the inherently industrial and commercial ends of synbio[95] raise questions about the kind of world we want to create, how widely shared visions of the future are and the purposes of this research.[96]

Applying RI here would involve early, inclusive deliberation on the directions and purposes of synbio research (who benefits? Should society support the bioeconomy?[97] What is synbio's role?); imagining the possible, plausible and desirable futures or societies it might create (will it consolidate existing inequalities?[98] Or contribute to the opposite?); defining socially desirable products or research funding priorities (does society desire biomedical, bioremediation or agricultural research, if any?). So far, applications of RI to synbio have included large-scale public dialogue exercises,[99] real-time TA[100] and establishing checkpoints at key stages in research, at which researchers consider specific ethical, social and regulatory questions and take various actions, for example re-evaluating the appropriateness of applicable IP regimes.[101]

The great potential of synbio runs through EU policy, promising to simplify production of useful products, improve efficiency and reduce the costs and uncertainty of traditional biotechnology.[102] Policy displays a cast-iron conviction that synbio represents an unmissable opportunity to enhance Europe's competitiveness.[103] Its potential to deliver products and solutions more quickly, providing an early return on investment is emphasised.[104] The EU wishes to lead in synbio research,[105] illustrating its general desire for any innovation. Commitments to undifferentiated innovation to achieve such economic goals[106] represent aspirations in conflict with creating space for reflection and responsiveness to societal concerns especially since the speed and direction of synbio itself are amongst those concerns.[107]

III. REGULATING SYNTHETIC BIOLOGY

1. Scope and definition

While not uncontroversial, the EU's position holds that current EU regulation is fit to assess and manage the risks of short-term synbio applications and thereby ensure safety.[108] Mid- to long-term

[93] H. König et al., 'Synthetic Biology's Multiple Dimensions of Benefits and Risks: Implications for Governance and Policies' in Boldt, op. cit., n. 83, p. 219 and references therein.
[94] DG SANCO, *Synthetic Biology: From Science to Governance* (2010) 14, 26.
[95] id., p. 5.
[96] For example, D. Bhattachary et al., *Synthetic Biology Dialogue* (2010) 7.
[97] A. Stirling, 'Power, Truth and Progress: Towards Knowledge Democracies in Europe' in *Future Directions for Scientific Advice in Europe*, eds. J. Wilsdon and R. Doubleday (2015) 135–136.
[98] J. Stilgoe, 'Don't Shut the Door on the Synthetic Biology Debate' *Guardian*, 8 May 2014 <http://www.theguardian.com/science/political-science/2014/may/08/dont-shut-the-door-on-the-synthetic-biology-debate>.
[99] For example, SYNENERGENE <https://www.synenergene.eu>.
[100] D. Stemerding et al., 'Future Making and Responsible Governance of Innovation in Synthetic Biology' (2019) 109 *Futures* 213.
[101] M.A. Bedau et al., 'Social and Ethical Checkpoints for Bottom-up Synthetic Biology, or Protocells' (2009) 3 *Systems and Synthetic Biology* 65.
[102] For example, Commission, op. cit., n. 85.
[103] Commission, id., p. 5.
[104] For example, ERASynBio, *Next Steps for European Synthetic Biology: A Strategic Vision from ERASynBio* (2014).
[105] For example, id., pp. 4, 13.
[106] For example, id., pp. 14 and references therein, 25.
[107] Sykes and Macnaghten, op. cit., n. 48, p. 103.
[108] J. Robienski et al., 'Legal Aspects of Synthetic Biology' in Boldt, op. cit., n. 83, p. 127.

however, this regime will require adaptation.[109] Assuming safety is the primary value already marginalises other concerns which merit discussion and response.

Application to SOs depends on the definitions in the CUD, of 'genetically modified micro-organism' (GMM)[110] and in the DRD, of 'genetically modified organism' (GMO).[111] The CUD concerns the use of GMMs in laboratory-based research involving the GM techniques specified therein. Non-food/feed GM products[112] destined for trade on the internal market 'as or in products',[113] for example, seeds for cultivation, biosensors or SOs intended for environmental decontamination, require authorisation under the DRD. The definitions currently cover synbio because the methods employed and the more imminent outputs of synbio resemble familiar GM techniques and their products.[114]

However, these definitions may not necessarily cover some longer-term developments in synbio.[115] For example, organisms not capable of self-replication could escape the definitions and fall outside the regulatory regime.[116] This has implications for risk assessment which, under the current regime is partially based on a comparative analysis between the GMO (or SO) and existing non-GM counterparts. Thus, the more artificial the organism and the corresponding unavailability of natural comparators, the more unreliable comparative risk assessment becomes.[117] Furthermore, an organism composed of non-natural DNA molecules may not be classified as 'genetically modified' and may therefore fall outside the regulation.[118] Indeed, the language of risk assessment developed for GM may become meaningless with advances in synbio[119] as, for example, concepts of 'donor' and 'acceptor' organisms become obsolete[120] for some SOs. Even the distinction between 'contained use' and 'deliberate release' is blurred.[121]

2. Contained Use Directive

The CUD 'lays down common measures for the contained use of' GMMs to protect human health and the environment.[122] These measures are justified firstly, by the EU's interest in developing biotechnology for economic gain[123] and secondly, by the likelihood that micro-organisms, once released, will reproduce and spread across national boundaries.[124] This requires common measures to evaluate and reduce the potential risks of contained use of GMMs[125] to ensure the safe

[109] König et al., op. cit., n. 93, p. 225.
[110] CUD, Article 2(a)-(b).
[111] DRD, Article 2(1)-(2).
[112] Products for food/feed use require authorisation under Regulation (EC) No. 1829/2003 on GM Food and Feed [2003] OJ L268/1. See Lee, op. cit. (2008), n. 4, p. 65 on the relationship with the DRD.
[113] DRD, Article 1.
[114] Pauwels et al., op. cit., n. 81, p. 30.
[115] id., p. 20. While synbio is not mentioned specifically, the CJEU's decision that organisms obtained by certain new plant breeding techniques constitute GMOs under the DRD may suggest willingness to interpret the term 'GMO' broadly, C-528/16 *Confédération paysanne v. Premier Ministre* ECLI:EU:C:2018:583.
[116] H-J. Buhk, 'Synthetic Biology and its Regulation in the European Union' (2014) 31 *New Biotechnology* 528, at 530.
[117] J.Y. Zhang et al., *The Transnational Governance of Synthetic Biology: Scientific Uncertainty, Cross-Borderness and the "Art" of Governance* (2011) 8.
[118] Pauwels et al., op. cit., n. 81, p. 31.
[119] Zhang et al., op. cit., n. 117, p. 8.
[120] H. Torgersen, 'Synthetic Biology in Society: Learning from Past Experience?' (2009) 3 *Systems and Synthetic Biology* 9, at 13.
[121] C. Marris and C. Jefferson, '"Workshop on 'Synthetic Biology: Containment and Release of Engineered Micro-Organisms': Scoping Report"' (2013) 19–22.
[122] CUD, Article 1.
[123] CUD, Recital 4.
[124] CUD, Recital 7.
[125] CUD, Recital 8.

development of biotechnology in the EU. Reflecting the dominant policy framings of innovation discussed in section I, the regime's foundational principles are facilitating economic progress in Europe and ensuring safety.

Under Article 4, the contained use in question is assessed and classified according to its level of risk and a level of containment is assigned. All first time contained uses and subsequent contained uses of low, moderate and high risk must be notified to the competent authority.[126] Containment and other protective measures are selected on the basis of the level identified, taking into account other considerations including 'the characteristics of the environment likely to be exposed' and of the activity itself, for example its scale. These may alter the level of risk identified.[127] This analysis results in assigning the activity in question to a particular risk class,[128] on the basis of which premises are licensed.[129] Although assignment to a risk class concerns safety, a normative question,[130] the CUD establishes it as a technical exercise conducted almost entirely using scientific risk assessment.[131]

Research-related, 'non-risk' concerns may influence societal attitudes to risk.[132] However, there is currently no room to consider such concerns or for more inclusive debate on characteristics of the environment likely to be exposed even though this would seem an appropriate subject for discussion. Higher risk contained uses trigger enhanced information obligations in the notification including the purpose and expected results of the contained use.[133] The competent authority may suspend, terminate, or adjust the conditions of the contained use where it poses risks which may have 'significant consequences'.[134] However, it is unclear how this information will be used in decision-making, who has access to it and 'significant consequences' is undefined. Legislation contributes to the context within which innovators must work[135] and the content of regulation may influence the actions of researchers upstream.[136] Where hard law prioritises safety, it could make expert-defined safety matters the only matters researchers feel compelled to heed, when further reflection on research aims and potential consequences could be salutary.

Article 12 allows Member States, where they consider it appropriate, to provide for public consultation on 'aspects of the proposed contained use'. However, consultation is not an obligation, the aspects consulted upon may not coincide with societal concerns and, where concerns are expressed, Member States are not required to consider the consultation responses in their ultimate decision. Potential for inclusive debate is thus limited.

The narrow focus on risk supports the CUD's ultimate aims to ensure safety and realise the economic benefits of biotechnology innovation. Regulation pursuing safety may reassure publics; indeed, containing technology can be as much about containing public fear.[137] Ultimately, the CUD may be an unsuitable instrument for a more ambitious approach; tighter or laxer containment measures are not

[126] CUD, Articles 6, 8(1) and 9(1).
[127] CUD, Annex III, para 7.
[128] CUD Annex III, para 8.
[129] CUD, Articles 6-10.
[130] Fisher, op. cit., n. 3, pp. 8–9.
[131] C. Landfried, 'The European Regulation of Biotechnology by Polycratic Governance' in *EU Committees: Social Regulation, Law and Politics*, eds. C. Joerges and E. Vos (1999) 178. This observation, made regarding the CUD's predecessor directive, applies equally here.
[132] Wynne, op. cit., n. 12.
[133] CUD, Annex V, Part C.
[134] CUD, Article 11(2).
[135] Asante et al., op. cit., n. 31, pp. 25.
[136] Stemerding et al., op. cit., n. 100, p. 217.
[137] S. Jasanoff and S-H. Kim, 'Containing the Atom: Sociotechnical Imaginaries and Nuclear Power in the United States and South Korea' (2009) 47 *Minerva* 119.

necessarily apt to respond to socio-economic or ethical concerns. As such, alone, it is insufficient to accommodate the wider issues and ambitions of synbio.

3. Deliberate Release Directive

The DRD seeks 'to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment'.[138] This aim applies to placing GMOs on the market 'as or in products'.[139] Like the CUD, the principles underlying the DRD relate to facilitating industrial development and ensuring safety. Living organisms released into the environment may reproduce and cross national borders,[140] indicating an EU level response. Approximation of national laws is also required to 'ensure the safe development of industrial products utilising GMOs',[141] emphasising both the economic and safety advantages of harmonised regulation.

3.3.1 Implementing inclusion

Article 13 requires applicants to submit a notification, including an environmental risk assessment (ERA)[142] and summary notification,[143] to the competent authority of the Member State in which it intends to market the GMO.[144] The Member State must compile an assessment report stating whether or not the GMO should be placed on the market.[145] Where the Commission or other Member State presents a reasoned objection[146] which cannot be resolved,[147] the decision goes to comitology.[148] If the objection concerns the risks of GMOs to human health or the environment, the Commission must consult the European Food Safety Authority (EFSA).[149] EFSA must make public its scientific opinions, along with the notification and other relevant information, subject to confidentiality provisions.[150] There is however, currently no obligation on the Commission to take EFSA's opinion into account.

Article 24 allows 30 days for consultation on the summary notification and assessment report. This attempt, criticised elsewhere,[151] to rectify the lack of opportunities for public involvement in the previous regime[152] remains narrow, restrictive and unambitious. Most importantly, the DRD establishes a downstream, pre-market authorisation process. While notification occurs earlier than under the previous Directive,[153] potentially allowing discussion between Member States 'before positions are entrenched',[154] consultation only happens following the ERA and Member State

[138] DRD, Article 1.
[139] DRD, Part C.
[140] DRD, Recital 4.
[141] DRD, Recital 7.
[142] DRD, Article 13(2)(b).
[143] DRD, Article 13(2)(h).
[144] DRD, Article 13(2).
[145] DRD, Article 14.
[146] DRD, Article 15(1).
[147] DRD, Article 15(2).
[148] DRD, Articles 18(1) and 30(2).
[149] DRD, Article 28.
[150] DRD, Article 28(4).
[151] For example, M.P. Ferretti, 'Why Public Participation in Risk Regulation? The Case of Authorizing GMO Products in the European Union' (2007) 16 *Science as Culture* 377; P. Dąbrowska, 'Civil Society Involvement in the EU Regulations on GMOs: From the Design of a Participatory Garden to Growing Trees of European Public Debate' (2007) 3 *J. of Civil Society* 287; Lee, op. cit. (2008), n. 4, p. 82; Ahteensuu and Siipi, op. cit., n. 50.
[152] Dąbrowska, id., pp. 287, 294.
[153] Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms [1990] OJ L117/15.
[154] Lee, op. cit. (2008), n. 4, pp. 65–66.

assessment report, long after research priorities and trajectories have settled. It therefore occurs too late to influence upstream decisions or open up broader questions about synbio.

This consultation procedure suggests potential for publics to air concerns regarding the relevant GMO/SO. However, comments are only permitted on the information contained in the summary notification.[155] Ethical or political issues fall outside the scope of the consultation, indicating the inability of this procedure to capture public concerns.[156] Moreover, engaging publics in decisions where assessments of risk are contested should explicitly recognise the contingency of expert evaluations of risk and the existence and validity of public evaluations of risk, otherwise much of its potential benefit could be lost. The DRD does recognise the importance of non-technical values, for example ethics, and provides for consultation of the European Group on Ethics in Science and New Technologies.[157] However, this provision seeks expert views on ethics rather than the exploration of wider stakeholder and public ethical concerns and it is unclear generally how ethics might affect decision-making in practice.[158] The overall emphasis on expert risk assessment and the narrowness of the consultation exercise means that broader, non-scientific concerns may not register.[159]

3.3.2 Opting-out

Directive 2015/412 amended the DRD in response, partly, to deficiencies in the regulatory framework, including chronic deadlock in comitology,[160] and to grant Member States greater flexibility to respond to their specific circumstances.[161] Under Article 26b(1), a Member State may, during the authorisation procedure, 'demand that the geographical scope of the… authorisation be adjusted' to exclude all or part of its territory from cultivation. Alternatively, following authorisation, Members States may restrict or prohibit cultivation of a single or group of GMOs in all or part of their territory.[162] Such measures must conform with EU law, be 'reasoned, proportional and non-discriminatory… and based on compelling grounds' for example environmental policy objectives, socio-economic impacts and public policy. Measures must not conflict with the ERA.[163] The opt-out does 'not affect the free circulation of authorised GMOs as, or in, products'.[164]

Granting a procedurally flexible, wide competence to Member States to restrict cultivation on numerous grounds without the need for supporting scientific evidence,[165] though limited, is potentially significant both for its recognition of diverse (sub-)national interests and values and as an attempt to embed that political dimension in the regulatory process.[166]

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[155] DRD, Article 24(1).
[156] Ferretti, op. cit., n. 151, pp. 384–389.
[157] For example, DRD, Article 29. Lee, op. cit., n. 26, p. 222.
[158] Lee, op. cit. (2008), n. 4, pp. 81–82.
[159] id., pp. 80-83.
[160] See S. Poli, 'The Reform of the EU Legislation on GMOs: A Journey to an Unknown Destination?' (2015) 6 *European J. of Risk Regulation* 559; M. Weimer, 'What Price Flexibility? - The Recent Commission Proposal to Allow for National "Opt-Outs" on GMO Cultivation under the Deliberate Release Directive and the Comitology Reform Post-Lisbon' (2010) 1 *European J. of Risk Regulation* 345, at 346–347.
[161] Directive 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory [2015] OJ L68/1, Recital 6.
[162] DRD, Article 26b(3).
[163] Conducted under either Regulation (EC) No. 1829/2003, op. cit., n. 112 or the DRD (Article 26b(3)).
[164] DRD, Article 26b(8).
[165] DRD, Article 26b(3); Poli, op. cit., n. 160, pp. 563–564.
[166] M. Lee, 'GMOs in the Internal Market: New Legislation on National Flexibility' (2016) 79 *The Modern Law Rev.* 317, at 332, 334–335.

Concern remains, however, that the reform seeks to protect the sanctity of EU risk assessment in decisions regarding placing on the market by arrogating consideration of safety concerns solely to the EU level and comitology as separate from, and untainted by, 'other concerns', now assigned to Member States.[167] In essence, while the reform could facilitate inclusion of different perspectives in some areas of regulation, risk assessment itself remains isolated, thereby preserving many of its problems and leaving unacknowledged the diverse attitudes to biotechnology and associated risks among Member States,[168] bound by its conclusions.[169] Largely excluding political, normative debate and other perspectives in favour of a single universal definition of safety here may further strengthen the technocratic nature of the EU's approach to GMO/SO authorisation, entrench artificial dichotomies between facts and values and de-politicise decisions which are profoundly political.[170] Furthermore, as Article 26b applies only to cultivation, neglects diverse national values and voices in the majority of applications not seeking authorisation for cultivation, deadlocked in comitology.[171]

Member State regulation on Article 26b(3) grounds must comply with internal market law and provide supporting evidence, if challenged. The application of internal market law could place significant restraints on this new flexibility,[172] perhaps reasonably so given the potential destabilising risks of multiple opt-outs.[173] The hope is that the Court of Justice respects the spirit of Directive 2015/412 and resists too strict an approach to adjudicating national opt-outs.[174] Likewise, while Member States would likely need to present a more convincing case than did Poland when defending its prohibition on marketing GM seeds on its territory,[175] 'diverse evidence should be acceptable'.[176] However, the reform could encourage equally reductive and expertise-driven methodologies as risk assessment to generate the necessary evidence and the Commission's indications of acceptable evidence do not suggest opening up decision-making overall.[177]

Finally, though applicable post-authorisation, the list of 'compelling grounds' in Article 26b(3) encompasses a wide range of concerns about the implications of biotechnology. While Article 26b(3) omits public opposition as a ground and makes no explicit provision for public participation, it is not prohibited, allowing Member States to engage with civil society. Indeed, the Commission anticipates that Member States will use the reform to respond to citizens' concerns and increase public involvement in national and regional decision-making.[178] This is promising in terms of allowing some

[167] K. Zurek, 'Indicating Reasons for National GM "Opt-Outs": The Way Forward or a Dead End Street?' (2011) 2 *European J. of Risk Regulation* 241, at 243; Directive 2015/412, Recital 14.
[168] G. Gaskell et al., *Europeans and Biotechnology in 2010: Winds of Change?* (2010).
[169] Though arguments regarding the acceptability of a risk based on, for example, uncertainty combined with distributional effects, are feasible, Lee, op. cit., n. 166, p. 328.
[170] id., pp. 333–337.
[171] M. Lee, 'The Ambiguity of Multi-Level Governance and (De-)Harmonisation in EU Environmental Law' (2013) 15 *Cambridge Yearbook of European Legal Studies* 357, at 373.
[172] N. de Sadeleer, 'Marketing and Cultivation of GMOs in the EU: An Uncertain Balance between Centrifugal and Centripetal Forces' (2015) 6 *European J. of Risk Regulation* 532.
[173] S.H. Morris and C. Spillane, 'EU GM Crop Regulation: A Road to Resolution or a Regulatory Roundabout?' (2010) 1 *European J. of Risk Regulation* 359, pp. 365–366; Poli, op. cit., n. 160, p. 572. So far, 121 demands for geographical restrictions by 19 Member States have been agreed: < https://ec.europa.eu/food/plants/genetically-modified-organisms/gmo-authorisation/gmo-authorisations-cultivation/restrictions-geographical-scope-gmo-applicationsauthorisations-eu-countries-demands-and-outcomes_en>.
[174] Lee, op. cit., n. 166.
[175] Poli, op. cit., n. 160, p. 571; Case C-165/08 *Commission v. Poland* [2009] ECR I-06843.
[176] Lee, op. cit., n. 166, p. 338.
[177] id., pp. 337–339.
[178] Commission, 'Proposal for a Regulation Amending Directive 2001/18/EC as Regards the Possibility for the Member States to Restrict or Prohibit the Cultivation of GMOs in Their Territory COM(2010) 375 Final' 5–6; id., p. 339.

space for public debate. In addition, the need for Member States to collaborate with industry, each other and the EU institutions during and after authorisation could also help create space for political debate.[179] However, any such activities are likely to occur 'downstream' meaning limited potential to open up synbio when innovation trajectories might still be influenced.

Most importantly perhaps, the reform seeks to facilitate authorisation for trade and the 'smooth functioning of the internal market',[180] potentially extinguishing space for deliberation on deeper questions including the need for, purposes of and motivations behind the technology and the kind of society it could create, especially where, as seems likely, EFSA's epistemic authority persists.[181] Retaining regulation of placing GMOs/SOs on the market at EU level to preserve the internal market[182] suggests the retention too of the DRD's fundamental market logic, guaranteed by EFSA's centralised expert risk assessments.[183]

3.3.3 Summary

The legislation examined is ill-equipped to accommodate concerns around synbio. The limited participation provisions and Article 26b do little to enable deliberation or challenge the market imperative, reflecting dominant policy framings and expectations of innovation. The focus on product authorisation and ensuring safety expresses a 'technology-neutral' approach to governing technology, reinforcing the traditional division of moral labour.[184] Some space for inclusive national decision-making exists. However, explicit provision for integrating broader concerns into regulatory decision-making is largely absent.

Concerns denied expression in existing structures can derail a technology, hence the need for different or additional frameworks, forums and soft instruments to open up research and innovation. Indeed, desire to avoid repeating the GM experience has driven many subsequent governance initiatives,[185] although not all demonstrate genuine potential to influence innovation trajectories. Both soft and hard instruments are necessary and hybrid approaches offer significant benefits for governing emerging technology. If conflicts are cooled upstream, controversy may burden regulatory decision-making less. There are, however, significant weaknesses, as discussed in the following section.

IV. SOFT GOVERNANCE OF EMERGING TECHNOLOGY

As Lee and Petts demonstrate, the law offers many instruments for regulating innovation and its outputs, including licences, pre-market authorisation, restrictions and liability regimes. The effectiveness of these tools however, is often limited by, for example, uncertainty over potential risks, difficulties proving causation and regulators' resources. Moreover, they cannot accommodate fundamental questions over need, motivation and purpose.[186] When regulating emerging technologies, therefore, flexible self-regulation or soft law constitutes a good starting point, perhaps leading eventually to hard regulation based on the knowledge gained.[187]

[179] Lee, id., p. 337.
[180] Directive 2015/412, Recital 8.
[181] M. Weimer, 'Risk Regulation and Deliberation in EU Administrative Governance—GMO Regulation and Its Reform' (2015) 21 *European Law J.* 622.
[182] Directive 2015/412, Recital 6.
[183] H. Gottweis, 'Participation and the New Governance of Life' (2008) 3 *BioSocieties* 265, at 279–280.
[184] von Schomberg, op. cit., n. 61, p. 14.
[185] See, for example, Wilsdon and Willis, op. cit., n. 5.
[186] Lee and Petts, op. cit., n. 6.
[187] id., pp. 154–155.

Use of soft law is a key feature of 'new governance', now well-established across many EU policy sectors.[188] New governance is also characterised by the sharing of responsibility among multiple different actors, in preference to consolidation in a centralised state, and offers a third way between 'command and control' regulation and deregulation, recognising the limitations of private markets in pursing public interests.[189] The literature defining and exploring 'soft' law or regulation *per se* as well as its relationship to 'hard' law or regulation and the limitations of each, is enormous and reveals deep contestation.[190] However, it suffices here to define 'soft regulation' broadly, as rules with normative content and which are 'understood to shape expectations of appropriate behaviour more strongly than mere political or social understandings'[191] but which are not legally binding,[192] for example guidelines and codes. Soft instruments may be employed pre- or post-legislation.[193]

The use of soft mechanisms, and indeed the existence of hybridity, in technology regulation is, of course, not new.[194] In the case of biotechnology, self-regulation dates back at least to the 1975 Asilomar Conference on recombinant DNA. 'New' scientific governance describes the increasing use of soft mechanisms and processes, particularly public dialogue and engagement, to govern science and innovation.[195] Soft approaches to governing technology and innovation are now pervasive.[196] In terms of implementing RI, soft governance mechanisms which institutionalise foresight, offer rich means to accomplish shared responsibility, public involvement and responsiveness to public interests by helping steer innovation towards socially desirable ends during development.[197]

For some, hybridity offers potential for interaction between hard and soft to mutually increase effectiveness, magnifying each other's strengths and mitigating weaknesses, rather than simply continuing in parallel.[198] This potential may manifest in various ways. Firstly, soft approaches may constitute a 'preparatory stage for legislation',[199] or stopgap measure.[200] For example, voluntary codes may become a 'first cut' of a new governance regime for an emerging technology.[201] Secondly, they may aid the implementation or application of existing legislation by fleshing out provisions or providing guidance on interpretation.[202] Where emerging technologies defy, as synbio does (see section II), existing definitional categories, guidance can help clarify what exactly is being regulated.

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[188] See contributions to G. de Búrca and J. Scott (eds.), *Law and New Governance in the EU and US* (2006).

[189] L. Trubek, 'New Governance Practices in US Health Care', in id., 246.

[190] For example, D. Trubek et al. ''Soft Law', 'Hard Law', and EU Integration', in de Búrca and Scott, op. cit., n. 188, 65-67 and references therein.

[191] K.W. Abbott et al., 'Soft Law Oversight Mechanisms for Nanotechnology', (2012) 52 *Jurimetrics* 279, at 286.

[192] Following Trubek et al., op. cit., n. 190, p. 65.

[193] S. Vaughan, *EU Chemicals Regulation: New Governance, Hybridity and REACH* (2015) on the latter, in particular.

[194] id.

[195] A. Irwin, 'The Politics of Talk: Coming to Terms with the "New" Scientific Governance' (2006) 36 *Social Studies of Science* 299.

[196] For example, G. Marchant, '"Soft Law" Governance of Artificial Intelligence' (2019) *UCLA AI Pulse Papers*; R. Hagemann, '"New Rules for New Frontiers: Regulating Emerging Technologies in an Era of Soft Law"' (2018) 57(2) *Washburn Law J.* 235.

[197] von Schomberg, op. cit., n. 61, pp. 27, 29-20.

[198] de Búrca and Scott, op. cit., n. 188, pp. 6-8.

[199] M.E. Gonçalves and M.I. Gameiro, 'Hard Law, Soft Law and Self-regulation: Seeking Better Governance for Science and Technology in the EU' (2011) Working Paper No. 2011/18, at 8.

[200] Hagemann, op. cit., n. 196, p. 239.

[201] D.M. Bowman and G.A. Hodge, 'Counting on Codes: An Examination of Transnational Codes as a Regulatory Governance Mechanism for Nanotechnologies' (2009) 3 *Regulation & Governance* 145.

[202] B. Dorbeck-Jung, 'Soft Regulation and Responsible Nanotechnological Development in the European Union: Regulating Occupational Health and Safety in the Netherlands' (2011) 2(3) *European. J. of Law and Technology* 1, at 4, 6; E. Stokes, 'Demand for Command: Responding to Technological Risks and Scientific Uncertainties' (2013) 21 *Medical Law Rev.* 11, at 27-28.

Thirdly, they may complement or supplement existing or imminent regulatory responses. Codes of conduct, for example the *EU Nano Code*,[203] may supplement existing regulation by setting out guidelines for compliance.

Soft and hybrid approaches have been pioneered in governing nanotechnology. This work is particularly relevant because firstly, like synbio, while existing EU legislation offered some cover for emerging nanotechnologies and despite the Commission's claims that existing legislation was adequate,[204] there remained gaps[205] and secondly, because much of the learning gained has informed the governance of other emerging technologies, including synbio.[206]

Soft instruments provide space for experimentation and the generation of knowledge.[207] Reporting schemes,[208] may seek to gather a broad range of data, aiding the regulator in understanding and anticipating issues, supporting decision-making including assessing whether, and what form of, regulation may be needed, while protecting industry freedom to operate, thus also offering commercial benefits.[209] More broadly, soft law may be regarded as better suiting the needs and purposes of science[210] with its traditional values of autonomy, independence and freedom[211] and history of self-regulation.

Soft approaches may respond more quickly to emerging problems.[212] For example, industry-developed standards may be more easily adopted than legislation as well as more effective, due to the greater concentration of knowledge in industry and capacity to secure industry buy-in.[213] They may also be better able to respond to public pressure for debate over controversial developments in science and technology[214] and to demonstrate early, anticipatory political or regulatory action in the face of such pressure.[215] The development of codes and guidelines offers opportunities to deliberate, identify potential problems and solutions and establish appropriate principles to guide ethical technology development.[216] The *EU Nano Code*, for example, was intended to encourage debate across all stakeholders and society at large.[217]

Finally, precautionary regulation is criticised for allegedly stifling technological innovation,[218] its vagueness[219] or for causing regulatory 'paralysis',[220] criticisms forcefully challenged.[221] However, soft approaches 'based on principles, guidelines and consultation' could ensure more nuanced application

[203] *EU Nano Code*, op. cit., n. 73.
[204] Stokes, op. cit., n. 202, p. 23.
[205] E. Stokes, 'Regulating Nanotechnologies: Sizing up the Options' (2009) 29(2) *Legal Studies* 281.
[206] Fisher and Rip, op. cit., n. 38, p. 179.
[207] Stokes, op. cit., n. 202, p. 21.
[208] For example, DEFRA, *UK Voluntary Reporting Scheme for Engineered Nanoscale Materials* (2008).
[209] Stokes, op. cit., n. 202, pp. 23-25; Abbott et al., op. cit., n. 191, pp. 300-1.
[210] Gonçalves and Gameiro, op. cit., n. 199, p. 3.
[211] For example, M. Polanyi, 'The Republic of Science: Its Political and Economic Theory' (1962) 1 *Minerva* 54.
[212] Abbott et al., op. cit., n. 191, p. 301.
[213] Y.A. Stevens, 'Soft Law Governance: A Historical Perspective from Life-Science Technologies' (2020) 61 *Jurimetrics* 121, at 126.
[214] Gonçalves and Gameiro, op. cit., n. 199, p. 4.
[215] Hagemann, op. cit., n. 196, p. 254.
[216] Abbott et al., op. cit., n. 191, pp. 287-8.
[217] *EU Nano Code*, op. cit., n. 73, paragraph 8.
[218] M. Dekkers et al., *The Innovation Principle: Stimulating Economic Recovery* (Brussels 2013).
[219] G.E. Marchant, 'From General Policy to Legal Rule: Aspirations and Limitations of the Precautionary Principle' (2003) 111(14) *Environmental Health Perspectives* 1799.
[220] C. Sunstein, *Risk and Reason: Safety, Law, and the Environment* (2002) 102-105.
[221] A. Stirling, 'Precaution in the Governance of Technology' in Brownsword et al., op. cit., n. 3.

of the precautionary principle than regulation, helping for example to address its vagueness.[222] In RI terms, the precautionary principle may be regarded as provoking, rather than constraining, innovation by incentivising consideration of alternatives, pursuing new risk research or identifying knowledge gaps.[223] It may steer, rather than stop, innovation[224] – potential which soft instruments may be better equipped to realise.

Overall, more flexible, participatory and reflexive modes of governance are regarded as better able to respond to complex, contested and rapidly evolving problems posed by new technological innovation, characterised by novelty, uncertainty and knowledge fragmented across multiple and changing state and non-state actors. Despite, however, the expectation that hybrid approaches to governance would encourage responsible technological development[225] and the benefits soft law offers for governing emerging technologies, there are limitations.

Compliance is crucial both for effectiveness and the 'output legitimacy' of soft or hybrid approaches.[226] While soft mechanisms may acquire teeth,[227] an obvious limitation is their unenforceability. Voluntary reporting schemes, for example, have seen low participation and submission of incomplete data.[228] While soft approaches offer flexibility in response to uncertainty, regulation may in fact be preferred as a source of stability, certainty and clarity.[229]

Soft approaches vary widely in their capacity to enhance accountability, responsibility and democracy in science and technology governance.[230] Some may set agendas and develop norms but make limited efforts to promote implementation or monitor and incentivise compliance.[231] Some may be created collaboratively, transparently, encourage inclusive deliberation and gather broader forms of information. Others may be closed, expert- or industry-driven processes, which may undermine their credibility, independence and legitimacy with knock-on effects for public trust and confidence.[232] Public engagement exercises on synbio, during the SYNENERGENE project, have exhibited both tendencies and demonstrated potential both to reproduce dominant narratives and framings (economics, technological progress etc.) and elicit new framings.[233] Soft approaches may respond to public concerns though the risk of whitewashing exists and they may not provide the same reassurance as hard regulation.[234] They may encourage anticipation and reflection on the broader direction of research and innovation, or equally retain a narrow focus on instrumental risks,[235] potentially bypassing political debate.[236] Indeed, soft law tends to be limited to preparing for, or

[222] Abbott et al., op. cit., n. 191, p. 301.
[223] von Schomberg, op. cit., n. 35, pp. 63, 67.
[224] A. Stirling, 'Making Choices in the Face of Uncertainty: Strengthening Innovation Democracy' in *Annual Report of the Government Chief Scientific Adviser, Innovation: Managing Risk, Not Avoiding It. Evidence and Case Studies* (2014).
[225] Dorbeck-Jung, op. cit., n. 202, p. 1.
[226] S. Arnaldi, 'Changing Me Softly: Making Sense of Soft Regulation and Compliance in the Italian Nanotechnology Sector' (2017) 11 *Nanoethics* 3, at 6.
[227] For example, D.J. Fiorino, *Voluntary Initiatives, Regulation, and Nanotechnology Oversight: Charting a Path* (2010) 15.
[228] Abbott et al., op. cit., n. 191, pp. 292-3, 303.
[229] Stokes, op. cit., n. 202, p. 39.
[230] M. Kurath, 'Nanotechnology Governance Accountability and Democracy in New Modes of Regulation and Deliberation' (2009) 5(2) *Science, Technology & Innovation Studies* 87.
[231] Abbott et al., op. cit., n. 191, pp. 308-9.
[232] id., pp. 296, 307.
[233] A. Bauer and A. Bogner, 'Let's (Not) Talk about Synthetic Biology: Framing an Emerging Technology in Public and Stakeholder Dialogues' (2020) 29(5) *Public Understanding of Science* 492.
[234] Marchant, op. cit., n. 196, p. 4.
[235] DuPont and Environmental Defense, *Nano Risk Framework* (2007).
[236] Kurath, op. cit., n. 230; Abbott et al., op. cit., n. 191, pp. 287-307, 312.

complementing, hard law. Worse, it may act as a substitute[237] or to undermine the case for, or delay, regulation.[238]

Finally, the use of soft approaches is often fragmented, piecemeal and *ad hoc*.[239] The proliferation of potentially overlapping soft law programmes, in the absence of coordination, can create confusion, duplication, unnecessary complexity and inconsistency while leaving gaps in governance.[240] Ensuring their effectiveness requires clarity over how voluntary measures interact with the broader regulatory framework.[241] In the following section, I explore the implications of the weaknesses identified above for implementing RI across the entire governance continuum.

V. TRANSFORMING LAW FOR AND WITH RI

While soft and hard regulation each make crucial contributions to governing emerging technologies, further work is needed to ensure, at minimum, the increased effectiveness of hybrid governance, and more ambitiously, to aid RI's transformative aims.

Some characterise the relationship between new governance and hard law as consisting in a 'gap' in which the latter is largely impervious to the former. The law either lags or ignores developments in new governance 'which do not conform to its presuppositions, structures and requirements', meaning it may 'curtail or inhibit' experimental governance measures.[242] The operation and ideologies of existing legislative structures may constrain soft measures, undermining any transformative potential. As such, soft measures may succeed less where they work against, rather than aid, existing legislative structures.[243] For example, rather than transforming an existing regulatory approach, voluntary reporting may simply complement it by increasing a regulator's understanding of the issues and to support decisions already required.[244] This characterisation may most accurately describe the relationship between the regime described in section III and attempts to open up synbio innovation. These efforts are not acknowledged on the face of the legislation which lacks, by its nature, space to accommodate the types of issues governance activities seek to uncover. This is perhaps not surprising given the different assumptions underpinning the different types of interventions and the tensions between them, discussed above.

Conversely, policy and scholarship on innovation governance/RI, and the parade spurred of projects, guidelines, declarations and so on, rarely explicate their implications for risk regulation. EU policy refers to public dialogue influencing the funding and conduct of science.[245] Funded organisations are encouraged to show they have considered ethical, social, environmental and other issues[246] and to make the outcomes of public dialogue available to policy makers, stakeholders and the public.[247] However, public debates regarding desirable outcomes lack specific entry points in policy-making[248] and indications that such activities should influence regulatory decisions are rare. Soft mechanisms

[237] Kurath, id., p. 89.
[238] Fiorino, op. cit., n. 227, p. 39.
[239] G.E. Marchant and W. Wallach, 'Coordinating Technology Governance' (2015) *Issues in Science and Technology* 43, at 46.
[240] id., p. 44.
[241] Fiorino, op. cit., n. 227, pp. 39, 42.
[242] de Búrca and Scott, op. cit., n. 188, pp. 4-5.
[243] Stokes, op. cit., n. 202, pp. 37-38.
[244] id., pp. 25-26.
[245] For example, ERASynBio, *Activity Catalogue for Measures in Public Dialogue* (2013) 5–6.
[246] ERASynBio, op. cit., n. 104, p. 25.
[247] 'Synenergene' <http://www.synenergene.eu/>.
[248] von Schomberg, op. cit., n. 61, p. 14.

should work with hard law regulation throughout innovation processes,[249] offering genuine potential for coordination across the governance continuum. Indeed, the governance tools discussed in section I were developed to complement downstream regulation,[250] enabling the necessary burden-sharing by coupling, for example, more anticipatory activities with risk regulation. These tools and risk analysis should be continuous.[251] However, while myriad instruments exist for governing innovation at specific points in the continuum, fully integrated oversight may still face barriers.

With regard to furthering responsibility specifically, the capacity for soft approaches to contribute to responsible development may depend, *inter alia*, on an existing culture of social responsibility in the relevant sector.[252] However, RI has ambitions which transcend existing needs and cultures. While the various soft instruments promoting RI/responsibility, discussed above, represent some progress in implementing RI in funding, policy and research contexts, the institutionalisation of RI is challenging even where institutional commitment exists.[253] The terms 'responsible', 'responsible innovation' and 'responsible development' are inherently flexible with much resting on the definition of 'responsible'. 'Responsible development' can be defined narrowly, for example as 'the balancing of efforts to maximize the technology's positive contributions and to minimize its negative consequences';[254] a definition which raises further questions. Elsewhere, it may go undefined.[255] Some instruments offer a nuanced and sensitive interpretation of RI,[256] others less so. The degree to which innovators conceive of RI as incorporating responsibility to broader society varies according to a range of factors and ambitious interpretations may be absent.[257]

As discussed, innovation policy is traditionally dominated by assumptions regarding the purposes of innovation and the types of concerns worth addressing. These assumptions also underpin regulation, as shown in section III, creating a regime with potential to constrain efforts elsewhere. RI challenges those assumptions and seeks to transform innovation processes. Soft approaches have an important, likely increasing, role to play in implementing RI. However, hybrid governance of emerging technologies, as currently pursued, is insufficient to support RI's ambitions. The requirement is not simply to re-double efforts to ensure soft mechanisms increase the effectiveness of hard regulation, nor even mutually enhanced effectiveness, although those needs exist. In order to transform innovation processes, all elements of the 'governance continuum' – policy, soft approaches upstream and midstream and hard regulation – need to align in pursuit of RI's goals. A holistic approach to governance for RI means considering how hard regulation itself might need to change, for example replacing hard law constraints on the ambition driving soft instruments with new ways of interacting.

A goal of RI is that science and innovation pursue socially desirable outcomes, as defined through RI processes. The relevant legislation should reflect those desired outcomes, once defined, as the legislation will contribute to ensuring and overseeing their achievement and will indeed, form the context of innovation processes.[258] For example, and simplifying somewhat, RI activities around synbio could reveal a collective desire for synbio to be directed towards decontaminating the environment while guarding against the concentration of power in particular industries or countries. Regulation alone is unlikely to be able to achieve this. However, regulation which expresses those desired

[249] Lee and Petts, op. cit., n. 6, p. 151.
[250] Ozoliņa et al., op. cit., n. 14, pp. 14–15.
[251] R. Owen et al., 'Beyond Regulation: Risk Pricing and Responsible Innovation' (2009) 43 *Environmental Science & Technology* 6902, at 6903–6904.
[252] Dorbeck-Jung, op. cit., n. 202, p. 9.
[253] Owen et al., op. cit., n. 64.
[254] NRC, *A Matter of Size: Triennial Review of the National Nanotechnology Initiative* (2006).
[255] For example, *Responsible NanoCode*, op. cit., n. 74.
[256] For example, OECD, op. cit., n. 79.
[257] Asante et al., op. cit., n. 31, pp. 23-26.
[258] id., pp. 22, 25.

outcomes – in its regulatory purpose, the types of information and considerations to be weighed in decision-making (perhaps still including, but not limited to, safety and economic impacts) and potential requirements for assessing matters other than risk – will look different to the regulation, for example the CUD and DRD, we have now. Adapting thus entails such regulation relinquishing its traditional technology-neutral approach and exclusive focus on safety and realising economic benefits. RI, as well as constituting an end in itself, may offer a framework for pushing beyond existing hybrid approaches to governing innovation to something more ambitious and integrated. This is aspirational. However, it is important to acknowledge this need, though its realisation be distant.

Hard law is criticised for its inflexibility and slowness to adapt. But law, including that regulating technology, can also be reflexive and adaptable. As discussed in section III, opportunities in the CUD/DRD for opening up discussion are not entirely absent and the law can of course undergo significant revision to respond to changing circumstances, new learning and problems with its current operation, as indeed the DRD did. However, the CUD and DRD have little in-built space for adaptation to re-defined innovation trajectories or emerging desired outcomes for synbio and any flexibility they, and other technology regulation, exhibit will be constrained by their underpinning assumptions. Such assumptions may go too deep to make revision worthwhile or possible.

In terms of extending the ambitions of RI to regulation, there are claims that soft law may be better at promoting 'transformative processes of norm diffusion, persuasion and learning… by allowing a wider spectrum for deliberation in the governing process'.[259] In contrast to the 'gap thesis', some view the relationship between law and new governance as transformative, highlighting their capacity for 'reciprocal change',[260] or even that hybrid governance, as a 'fusion' of hard and soft, transforms the law itself, enhancing problem-solving and law-making.[261] This argument notes the role new governance plays in generating the context for law and in transforming the 'substantive content of certain legal norms or concepts'[262] and 'the way law is created and administered'.[263] There is evidence that governance processes can change assumptions underpinning legislation and, perhaps more importantly, the assumptions of relevant actors.[264] Soft instruments may be able to aid reflection on 'more entrenched aspects of the regulatory landscape'.[265] Concepts, such as responsibility, may be used as a value or objective to shape policy or principle to guide legislation, while also being given 'substance, shape and meaning' by new governance mechanisms, particularly deliberation.[266] New governance changes our understandings about what the law does or can do, away from creating rules to creating provisional legislative frameworks in which multiple actors elaborate and revise the rules.[267]

Harnessing the transformative potential of the interaction between soft and hard law for the purposes of RI means expanding RI itself to reflexively consider the entire governance continuum[268] including

[259] Trubek et al., op. cit., n. 190, pp. 75-76.
[260] C.F. Sabel and W.H. Simon, 'Epilogue: Accountability without Sovereignty' in de Búrca and Scott, op. cit., n. 188, p. 404.
[261] D.M. Trubek and L.G. Trubek, 'New Governance & Legal Regulation: Complementarity, Rivalry, and Transformation' (2007) 13(3) *Columbia J. of European Law* 539.
[262] de Búrca and Scott, op. cit., n. 188, pp. 9-10.
[263] Trubek, op. cit., n. 189, p. 246.
[264] W.H. Simon, Toyota Jurisprudence: Legal Theory and Rolling Rule Regimes' in de Búrca and Scott, op. cit., n. 188, pp. 60-61.
[265] E. Stokes and D. Bowman, 'Looking Back to the Future of Regulating New Technologies: The Cases of Nanotechnologies and Synthetic Biology' (2012) 2 *European J. of Risk Regulation* 235.
[266] By analogy with the concept of solidarity, C. Barnard, 'Solidarity and New Governance in Social Policy' in de Búrca and Scott, op. cit., n. 188.
[267] Sabel and Simon, op. cit., n. 260.
[268] Stilgoe et al., op. cit., n. 15, p. 1571.

regulation and underpinning assumptions. Aims would include ensuring a truly integrated hybrid approach to governance and that regulation does not constrain the effectiveness of soft, RI approaches. For example, appropriate soft mechanisms could be employed to anticipate the type of regulation appropriate for a given emerging technology, in which the overarching regulatory purpose and considerations and information to be weighed by decision-makers are also up for grabs. Policy-makers and legislators should participate early to enable reflection on the commitments and assumptions traditionally underpinning innovation policy and regulation, ensure regulation responds to learning and emerging priorities, including supporting progress towards the 'right impacts', and to build in provisions which allow flexibility and adaptability in order to enable ongoing responsiveness to developments as the technology emerges and evolves.

VI. CONCLUSION

RI constitutes a powerful framework for transforming innovation processes. It encompasses multiple tools to facilitate its different dimensions and in the short- to medium-term will likely be implemented using soft instruments. Synbio offers a useful case study to consider the limitations of existing hard regulation and to anticipate problems with implementing RI in that regulatory context and technology regulation generally. Soft instruments offer many benefits for governing emerging technologies. However, current hybrid approaches to technology governance reveal significant weaknesses, indicating a need to consider the entire governance continuum holistically in order to improve its effectiveness. Hybridity is likely to emerge in response to 'difficult and potentially contradictory imperatives' and be used to 'marry' potentially conflicting goals in a single system.[269] This may offer a partial, higher-level explanation for its presence in the controversial matter of governing technology which, as demonstrated, is traditionally underpinned by certain assumptions about, and the goals of, innovation and its governance, leading to tensions between RI's ambitions to transform and existing governance frameworks. These assumptions often go unexamined. Changing them, therefore, and dissolving tensions will be challenging, to put it mildly. Not doing so, however, throughout the governance continuum, may hinder RI's ability to transform. RI may be able to help address the limitations of hybrid approaches experienced to date through providing a framework for reflecting on those assumptions. This is therefore an invitation to those in both STS and legal academia – and beyond – to think collaboratively about the types of governance interventions, both soft and hard, required to support the transformation of innovation processes.

[269] Trubek et al., op. cit., n. 190, pp. 93-94.