

PROPORTIONATE AND ADAPTIVE GOVERNANCE OF INNOVATIVE TECHNOLOGIES (PAGIT)*

CASE STUDY: RESPONSIBLE GOVERNANCE OF INNOVATIVE TECHNOLOGIES

FINAL REPORT

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Acronyms

AREA approach	Anticipate, Engage, Reflect, Act
BEIS	Department for Business, Energy and Industrial Strategy
BSI	British Standards Institution
CSR	Corporate Social Responsibility
EC	European Commission
EFSA	European Food Safety Authority
ELSA	Ethical, legal and socioeconomic aspects
ELSI	Ethical, legal and socioeconomic implications
EPSRC	Engineering and Physical Sciences Research Council
FP7	Framework Programme 7 (EU Research Programme)
GM	Genetically modified
GMO	Genetically modified organism
H2020	Horizon 2020 (EU Research Programme)
ISO	International Standards Organisation
NGO	Non-Governmental Organisation
OECD	Organisation for Economic Cooperation and Development
PAGIT	Proportionate and adaptive governance of innovative technologies
R&D	Research and development
REng	Responsible engagement
RI	Responsible innovation
RR	Responsible research
RRI	Responsible research and innovation
TRL	Technology Readiness Level
TSB	Technology Strategy Board

1 Introduction

1.1 The PAGIT Framework and the role of Responsible Research and Innovation (RRI)

Innovation is expected to form the basis of national prosperity in the UK¹ and internationally², and the UK Industrial Strategy White Paper has set out ambitious plans for providing financial, organisational and structural support to the UK's most innovative sectors. However, these investments will fail to deliver the expected benefits unless they are accompanied by targeted initiatives to make governance systems³ more proportionate and adaptive to the needs of innovative technologies. Many of today's regulatory systems have evolved throughout the 20th century to become expensive, time consuming, rigid and difficult to adapt to the properties of 21st century innovation particularly, but not exclusively in the life sciences. This unaddressed barrier to translation leads to a waste of national resources and a drag on UK productivity that should no longer be acceptable.

The PAGIT framework⁴ is designed to deal with this translational deficit while continuing to ensure safety, quality and efficacy of innovative developments and also to take account of the UK's need to avoid regulatory challenges to international trading relationships. It builds on three principles to guide decision making - the **innovation principle**, developed by the European Risk Forum⁵ and subsequently adopted into EU policies⁶, and the associated regulatory **principles of proportionality and adaptation**⁷.

The *governance* of technologies has two components: (i) the policy and political structures and procedures that influence decisions about which technologies are developed and when and how they should be regulated and (ii) the regulatory systems themselves that ensure the safety, quality and efficacy of products and processes. The concept of Responsible Research and Innovation (RRI) is part of the first component, seen as part of the democratic process, providing a role for citizens and stakeholders in decision making about which technologies are developed and how they are developed and regulated. However, as with current regulatory systems, there are also a number of defects in the application of RRI so far to innovative technologies.

The PAGIT Framework includes responsible governance (RRI) related aspects of innovation alongside the regulatory elements (Figure 1) for several reasons. Societal concerns, particularly about disruptively innovative technologies, are likely to continue to be an issue, and any new approach to their regulation will need to undertake specific measures to maintain public confidence in the proposed future regulatory systems. Responsible leadership in the governance of innovation is increasingly about *not* being driven by the short-term minority interests and values of the most vocal societal elements. The more balanced, standards-based approach to the governance of innovative

¹ HM Government (2017) *Industrial Strategy: building a Britain fit for the future*. Nov. 2017, Cm 9528. (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/662541/industrial-strategy-white-paper-print-version.pdf)

² OECD (2015) *The Innovation Imperative: Contributing to Productivity, Growth and Well-Being*, OECD Publishing, Paris. DOI:<http://dx.doi.org/10.1787/9789264239814-en>

³ See Annex 4 for a definition of how we are using the term 'governance' in the PAGIT Project

⁴ 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>

⁵ European Risk Forum (ERF) (2015) *The Innovation Principle – Overview*. (http://www.riskforum.eu/uploads/2/5/7/1/25710097/innovation_principle_one_page_5_march_2015.pdf)

⁶ European Political Strategy Centre, (2016) *Opportunity Now: Europe's Mission to Innovate*. EPSC Strategic Notes, Issue 15, 5 July, 2016. (https://ec.europa.eu/epsc/sites/epsc/files/strategic_note_issue_15.pdf)

⁷ European Political Strategy Centre, (2016) *Towards an Innovation Principle Endorsed by Better Regulation*. EPSC Strategic Notes, Issue 14, 30 June 2016. https://ec.europa.eu/epsc/sites/epsc/files/strategic_note_issue_14.pdf

technologies proposed here considers the responsibility of all relevant actors incorporating the variety of interests and values that will need to coexist in any plural democracy.

This report first outlines the key features of the PAGIT Framework and the role of RR and RI within it. Section 2 outlines the case study objectives and the research approach and Section 3 offers a critical perspective on current approaches to RRI and outlines the rationale for the proposed PAGIT alternative. Section 4 summarises the discussions on this alternative approach held with project participants in interviews and a workshop. The proposed standards based approach to responsible governance and its implementation are outlined in Section 5 and Section 6 proposes recommendations for future action.

1.2 Disruptive and incremental innovation

A novel feature of the PAGIT Framework is its focus on the disruptive potential of an innovation and the sectoral location of that disruption. The UK Industrial Strategy White Paper recognises the particular need to support new industry sectors that will be disruptive or path-breaking in relation to established ways of working and to ensure that the innovations on which these sectors will be based are not unnecessarily restricted or delayed. At the same time it also recognises the need to support the incremental or path dependent innovations that will improve our international competitiveness in existing industry sectors.

Disruptive and incremental innovation are defined for the PAGIT Framework as follows⁸:

- **Incremental innovation** fits well with the current business model of a firm. It generates competitive advantage and contributes to the economy through more efficient use of resources, or elimination of wasteful or environmentally damaging practices. It is likely to have a pre-existing regulatory framework in place, will not lead to sectoral transformations and is unlikely to lead to stakeholder or citizen concerns or opposition.
- **Disruptive innovation** involves discontinuities in innovation pathways, requires new areas of research and development, creation of new modes of production and new markets. It can lead to sectoral transformations and the displacement of incumbent companies, and the creation of entirely new sectors with significant societal and economic benefits. There may be no obvious regulatory precedent to govern potential human and environmental safety issues and in some cases it may lead to citizen and stakeholder concerns from an early stage of development. For a disruptive innovation, there may be no existing business model on which a company can build, and there may also be a need to create a new value chain, or to create a new role in an existing value chain.

There is a common misconception that it is not possible to tell in the early stages of its development whether an innovative technology will be disruptive or incremental. This question is addressed in more detail in the PAGIT Framework Report and, although this is a question of intelligent Foresight with all the usual caveats about human Foresighting capabilities, such predictions can be reasonably accurate, given an intimate knowledge of the technology itself and of the competing industry sectors that could take on the role of developing and marketing it⁹. The Innogen Institute has developed methods and guidelines to predict where in sectoral value chains disruption will occur, which sectors will be disrupted, how and to what extent they will be disrupted, and the influence of future regulatory choices on these outcomes¹⁰.

⁸ Tait, J. (2007) Systemic Interactions in Life Science Innovation. *Technology Analysis and Strategic Management*, 19(3), 257-277, May 2007

⁹ Mitra, J., Tait, J., Mastroeni, M., Turner, M., Mountford, J., Bruce, K., (2014) Identifying Viable Regulatory and Innovation Pathways for Regenerative Medicine: A Case Study of Cultured Red Blood Cells, *New Biotechnology*, <http://www.sciencedirect.com/science/article/pii/S1871678414021293#>

¹⁰ <http://www.innogen.ac.uk/downloads/Innogen-Institute-Research-Outline.pdf>

A complicating factor, and one of the important reasons for developing the PAGIT Framework, is our observation that the early choice of regulatory system for a potentially disruptive technology can determine the extent to which it is indeed disruptive, and for which industry sector. One example of such an interaction is the development of GM crops, where the early choice to regulate the technology through chemicals-based regulatory systems meant that the technology was developed by the agrochemical industry sector for which it was seriously disruptive of research and development (R&D) processes, manufacturing capabilities, distribution systems and markets¹¹. The alternative being discussed in the 1980s was to regulate GM crops through the plant variety regulatory system, in which case it would probably have been developed by the seeds sector, where there would be little or no disruption of R&D, manufacture or markets.

If GM crops had been developed by the seeds sector, there would have been a different set of choices for early products on the market (probably not herbicide resistance) and a more diverse array of markets served, rather than only major commodity crops. Also, linked to the issue of responsible governance, there would probably have been a very different societal response to the technology. This understanding underlies our projection that, where there is potential disruption particularly market disruption arising from an innovative technology, it will be more likely to raise public concerns, or conversely to generate excitement and positive anticipation. This aspect also reinforces the emphasis here on consideration of how responsibility in innovation processes can be demonstrated by all key players involved.

1.3 The overall PAGIT Framework

The PAGIT framework decision process is related to the development stages of an innovation, described in terms of technology readiness levels (TRLs), increasingly used as a planning tool for innovation management¹². Applying this to the consideration of responsible behaviour, a distinction is made between the conduct of basic scientific research at TRLs 1 – 3 (RR), and the translational stages of innovation development at TRLs 4 – 9 (RI), from the early stages of development and testing through to market launch on a time scale that depends, among other things, on the nature of the regulatory system.

In keeping with much of the literature on RRI, this report refers to upstream and downstream processes. We use the term ‘upstream’ to apply to the stages of basic research that pre-date proof of concept for the technology, i.e. TRLs 1-3 (RR). ‘Downstream’ refers to subsequent development phases beyond TRL 4, through to market launch (RI), as shown in Figure 1.

As described in Section 3, there is already a large body of investigation and analysis on RRI with a relative lack of consideration of the needs of practical innovators. The approach developed here attempts to achieve a more equitable balance across the needs and desires of a broader range of stakeholders than current initiatives. It also recognises that RR-related initiatives carried out upstream in the development of an innovative technology can lead to its negative framing in the minds of citizens, a process that is then difficult to adjust at later stages of development even if new evidence on benefits and risks becomes available or if public opinion should change.

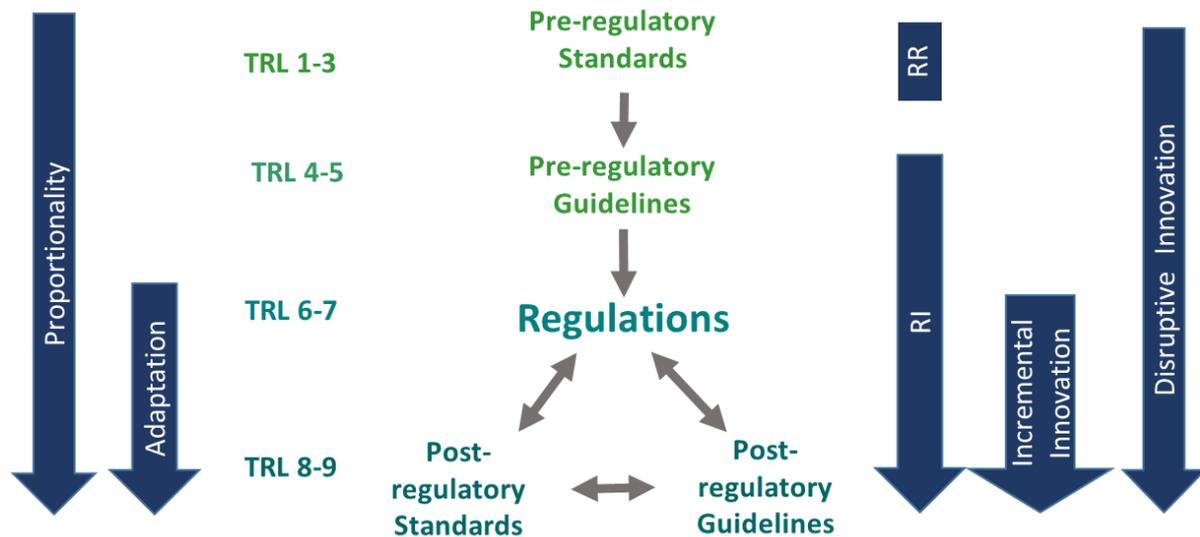
Alongside the focus on the extent of disruption as the primary basis for regulatory decision making on the governance of innovative technologies, a novel aspect of the Framework is the closer

¹¹ Tait, J. and Chataway, J. (2007) The governance of corporations, technological change and risk: examining industrial perspectives on the development of genetically modified crops. *Environment and Planning C: Government and Policy*, 25, 21-37

¹² EARTO (European Association of Research and Technology Organisations) (2014) *The TRL scale as a research and innovating policy tool*, EARTO recommendations. 30 April 2014. [http://www.earto.eu/fileadmin/content/03_Publications/The_TRL_Scale_as_a_R_I_Policy_Tool_-_EARTO_Recommendations_-_Final.pdf]

integration of standards into governance and regulatory systems to deliver on our three underlying principles: innovation, proportionality and adaptation (Figure 1).

Figure 1. PAGIT Framework



2 Project objectives and research approach

The project objectives were:

1. To scope a consensus responsibility standard¹³ (see Annex 4) including a **Responsible Innovation (RI)** standard applicable to company behaviour, and a standard for **Responsible Engagement (REng)** that applies to all stakeholders including innovators;
2. To open a dialogue with research, industry and policy/regulatory partners and other interested stakeholders.
3. To develop a plan for implementation of an overall responsibility standard.

The projected family of standards implied for the first objective has been modified considerably in the final proposed approach in Section 5, to remove linguistic confusion and to take account of the contributions of project participants.

There is considerable ambiguity in the terminology in this area. For example, EU projects and programmes on RRI have been mainly about Responsible Research (RR), and not innovation, while the UK Engineering and Physical Sciences Research Council (EPSRC) Responsible Innovation (RI) approach, given the Council's remit to fund scientific research, influences mainly RR. Most RRI related projects do not see the need to consider RR and RI as two differentiated areas of application, but for this project we have distinguished the concepts as follows (see Figure 1):

- The term 'responsible research' is relevant to the conduct of basic research prior to proof of concept (TRLs 1-3), in both public and private sectors.

¹³ Steedman, S. (2013) *Standards and synthetic biology: structuring knowledge to accelerate innovation*. EU Workshop in Synthetic Biology, 11 Oct., 2013. (<https://connect.innovateuk.org/documents/2826135/9165366/7+Scott+Steedman.pdf/763762eb-c49d-4436-8b28-69bdd03637e9;jsessionid=2B0AC4A4659678575BB695F6A164EB3F.2>).

- Beyond proof of concept ‘responsible innovation’ refers to the further development of innovative products or processes as they progress towards market readiness, from TRL4 onwards.

Semi-structured interviews were held with participants with interests and experience in RRI. Interviews engaged participants in discussion about how to frame an effective policy approach for RR and RI and the potential for standards to contribute to such an approach. A workshop was also held in London in March 2017 to identify where and how standards could contribute to the equitable acceptance of responsibility across the main players in the governance of innovative technologies; addressing questions related to achieving an optimum balance between the interests of government, industry and civil society. The workshop included four presentations followed by open plenary discussions.

Project participants all had experience of working in RRI-related roles from a range of perspectives: academic social scientists (5); academic natural scientists and research institute representatives (3); government policy makers, regulators and advisers on RRI-related questions (6); RRI related consultancies and think-tanks (3); companies working on synthetic biology-related developments (1); and agriculture-related organisations (2). Two workshop participants came from other EU countries (Sweden and Netherlands) and there were 3 interviewees from Sweden, Austria and Belgium. Participants were asked about their concerns related to RI in general, how responsibility standards might be developed and applied, how such standards could make governance systems more adaptive to the needs of both disruptive and incremental innovations, and the role that companies and regulators could play in this process. The small scale of the project means that firm conclusions cannot be drawn from its outcomes but they form a useful basis for future elaboration and development.

Interviews and workshop proceedings were recorded and transcribed with the permission of participants. In the analysis of these discussions (Section 4) anonymised participant quotes are italicised, where possible including information on the type of organisation represented. (From the recording of the workshop it was not always possible to identify the speaker.) The final draft of this report was circulated to participants, to check on the accuracy of the analysis in Section 4 and to offer other editorial comments and suggestions, and we are grateful for their very helpful inputs.

Annex 1 is the general description of the case study, sent to potential project participants along with the covering letter (Annex 2) and the questions to be discussed (Annex 3). Annex 4 gives definitions of the key concepts underlying this analysis.

3 Current RRI theory and practices

3.1 Critique of the EU approach to RRI

The focus on ensuring that science and innovation are practiced responsibly arose from social science funding streams in the US and the EU dealing with Ethical, Legal and Social Impacts or Aspects (ELSI/ELSA) of genomics related technologies, advocating the process of upstream engagement as a way of giving citizens and stakeholders a voice in decisions about the funding and conduct of research.

The first major ELSI initiative in 1989, funded as part of the Human Genome Project¹⁴, set the pattern for the extension of this form of social science analysis to many other areas of innovation, particularly in the life sciences. Conceived as a top-down funding agenda for the EU to shape the future of the *social sciences*, ELSA began to be identified as a specific research practice and became a required component of much of the *scientific research* funded by the EU. Social scientists used the opportunities ELSA programmes offered (e.g. in terms of proximity to life sciences research

¹⁴ <https://www.genome.gov/10001787/elsi-working-group/>

consortia) to strengthen the visibility and impact of their work¹⁵ and it therefore served as a set of public fora to address societal issues as perceived by the academic social science community and to attempt to shape future innovation trajectories through upstream engagement¹⁶.

Zwart *et al*¹⁷ have described how the ELSA agenda began to run out of steam around 2010 and was replaced in EU funding programmes by the concept of RRI, describing it as ‘a new initiative in the labelling arena’, with a high degree of continuity with ELSA in the academic staff and disciplines involved. Until very recently RRI researchers, as in the case of ELSA, have focused their attention almost entirely on scientific research (RR) rather than on innovation *per se* (RI), and on upstream engagement as a means to deliver the responsible behaviour that citizens are presumed to demand.

The focus of attention for RRI is mainly on potentially disruptive and hence contested technologies such as nanotechnology, stem cell therapies, nuclear technology, synthetic biology and more recently artificial intelligence. Most proponents of RRI claim that, by applying ethical considerations and deliberative public engagement to such technologies the innovation process can be made more efficient through better targeting of basic research funds, and that innovation outcomes will then be more beneficial to society¹⁸. However, that assumption has not been borne out by experience¹⁹.

Despite the preceding investment in the ELSA agenda and the lack of novelty in research conducted under the RRI label, the EU Framework Programme 7 (FP7) and the Horizon 2020 (H2020) research programmes have invested heavily in this area:

- FP7 projects, most receiving over a million Euros, included GREAT, Res- AGoRA, ProGRess, Responsibility, Synnergene, and RISE;
- the H2020 research programme in 2015, including only those calls with RRI in the title, had 21.8 M Euros of funding available²⁰; and
- the latest H2020 call under the ‘Science with and for Society’ heading has allocated over 42 M Euros for 14 RRI related projects²¹, with a stronger focus on industry leadership than previous funding rounds.

In the UK, social science researchers have had a prominent role in many of these EU projects and also in advising UK research councils on delivering their assumed commitment to RRI²². These EU

¹⁵ Stegmaier, P. 2009. The rock ‘n’ roll of knowledge co-production. Science and Society Series on convergence research. *EMBO Reports* 10(6):114–119.

¹⁶ Willis R., Wilsdon J. ‘See-through science – why public engagement needs to move upstream’. (London, UK: Demos, 2004)

¹⁷ Zwart, H., Landeweerd, L. and van Rooij, H. (2014) ‘Adapt or perish? Assessing the recent shift in the European research funding arena from ‘ELSI’ to ‘RRI’’. *Life Sciences, Society and Policy*, 10, (11), pp 1-19, DOI:10.1186/s40504-014-0011-x, <http://www.lsspjournal.com/content/10/1/11>

¹⁸ Tait, J. (2009) 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. (<http://www.nature.com/embor/journal/v10/n1s/pdf/embor2009138.pdf>)

¹⁹ Tait, J. and Barker, G., (2011) Global food security and the governance of modern biotechnologies: opportunities and challenges for Europe. *EMBO Reports*, 12, pp763-768. (<http://www.nature.com/embor/journal/v12/n8/pdf/embor2011135a.pdf>)

²⁰ EU Framework Programme for Research and Innovation, Horizon 2020, ‘Responsible Research and Innovation: a Cross-cutting Issue’. (DG RTD B7-Science with and for Society, 2014) https://ec.europa.eu/research/swafs/pdf/presentation_Galiay.pdf (accessed 12 March 2017).

²¹ Horizon 2020 ‘Work Programme 2016-2017: Science with and for Society’, (European Commission, 2016) http://ec.europa.eu/research/participants/data/ref/h2020/wp/2016_2017/main/h2020-wp1617-swfs_en.pdf, accessed 12 March 2017.

²² Stilgoe, J. and Kearnes, M. ‘Nanodialogues Report: engaging research councils’ (London, Demos, 2007) <http://webarchive.nationalarchives.gov.uk/20091004173547/http://www.epsrc.ac.uk/CMSWeb/Downloads/Other/NanodialogueEngagingResearchCouncilsReport.pdf> (accessed 12 March 2017).

funding initiatives have positioned RRI as an important component of research funds that address global challenges, and research scientists are expected to demonstrate responsible behavior; also the requirement is gradually being introduced to innovating companies across a range of sectors²³.

The European Commissioner for Research, Innovation and Science, Maire Geoghegan-Quinn has described RRI as contributing to the creation of “a smarter, greener economy where our prosperity will come from research and innovation ... [and] ... research and innovation must respond to the needs and ambitions of society, reflect its values and be responsible”. He specified the following as key elements of EU RRI programmes²⁴:

- (i) Engagement;
- (ii) Gender equality;
- (iii) Science education;
- (iv) Open access;
- (v) Ethics; and
- (vi) Governance.

Engagement and governance can be seen as relevant to innovation but for the other elements there is no reason to link them specifically to an innovation agenda. They should be seen as policy responsibilities of governments (gender equality, science education) or general strategic responsibilities of companies (open access, ethics), to be implemented through the standard operating procedures of all companies, not just those involved in developing specific innovations.

A report for the European Commission (EC)²⁵ defines RRI as “an approach that anticipates and assesses potential implications and societal expectations with regard to research and innovation, with the aim to foster the design of inclusive and sustainable research and innovation” and specifies that “The RRI approach has to be a key part of the research and innovation process and should be established as a collective, inclusive and system-wide approach.”

Von Schomberg²⁶ and Owen²⁷ acknowledge the tensions inherent in attempting to guide research and innovation towards ‘the right impacts’ given the inevitable diversity, and sometimes mutual incompatibility, of societal interests, concerns and values, and it has not yet proved possible to separate the discourses surrounding RRI from an underlying politically defined conception of these ‘right impacts’. This political overlay on the concept of RRI²⁸ is amplified by the uncertainty inherent in any early stage foresight on the outcomes of research and development processes. However, most researchers working on RRI-related projects retain an unrealistic optimism that upstream societal engagement can indeed deliver a process of anticipatory governance leading to societal

²³ EU (2012) Responsible Research and Innovation: Europe’s ability to respond to societal challenges. (https://ec.europa.eu/research/swafs/pdf/pub_public_engagement/responsible-research-and-innovation-leaflet_en.pdf, accessed 12th March 2017)

²⁴ Maire Geoghegan-Quinn (2012) *Responsible Research and Innovation – Europe’s ability to respond to societal challenges*. (https://ec.europa.eu/research/swafs/pdf/pub_public_engagement/responsible-research-and-innovation-leaflet_en.pdf)

²⁵ Van den Hoven, J. 2013. *Options for Strengthening Responsible Research and Innovation*. Report of the Expert Group on the State of Art in Europe on Responsible Research and Innovation. Brussels: European Commission (https://ec.europa.eu/research/science-society/document_library/pdf_06/options-for-strengthening_en.pdf (accessed 22/10/17)).

²⁶ Von Schomberg, R. (2011) Prospects for Technology Assessment in a framework of responsible research and innovation. In: M. Dusseldorp and R. Beecroft (eds). *Technikfolgen abschätzen lehren: Bildungspotenziale transdisziplinärer Methoden*. London: Springer Verlag.

²⁷ Owen, R. (2012) From co-operative values to responsible innovation, *Projectics /Proyética / Projectique* 2012/2 (n°11-12), p. 5-12. DOI 10.3917/proj.011.0005.

²⁸ Tait, J. (2017) From Responsible Research (RR) to Responsible Innovation (RI): challenges in implementation. *Engineering Biology*. doi: 10.1049/enb.2017.0010.

consensus on the potential value of future innovations. The incorporation of a standard for engagement within the PAGIT Framework is intended, among other things, to counter the potential for politically motivated influences on the conduct and interpretation of RRI-related engagement and dialogue.

The rigid specification and large scale of EU RRI research programmes have created an academic culture among social scientists that is focused on the incumbent, strongly promoted EU paradigm, in the Kuhnian sense²⁹. One result of this is the similarity among the research projects funded under the FP7 and H2020 research programmes, each developing minor variations on the RRI/ELSA theme, involving ‘frameworks’ and ‘roadmaps’ to implement the EU specification of the meaning of the RRI concept. This significant scale of research funding has not, as might have been hoped, fostered the emergence of a broad range of competing ideas about how to meet the challenges of guiding research and innovation on new areas of science and technology. As a result, there has been little or no challenge to, or engagement with, the foundational concepts of RRI as specified by the EU. This is a paradigm that is ripe for challenge on the basis of its narrow political and academic origins³⁰.

3.2 UK initiatives in RRI

The PAGIT approach to RRI draws on two UK initiatives by the EPSRC³¹ and the Technology Strategy Board (TSB)³².

The TSB Responsible Innovation Framework (RIF) considered the specific needs of innovators and implemented RI in its synthetic biology translational support projects, aiming “... to fund projects where the ‘anticipated commercial use’ of the project outcomes meets, on the balance of positive and negative drivers, the standards outlined ... for responsible innovation”; and “... to help companies **anticipate and give responsible consideration** to the **intended** and **potential unintended** impacts of the commercial development and use of the technology, including the potential for misuse, **before the work begins**” (TSB emphases). It was directed to the activities of companies at all stages in the innovation process, from new spin-out companies to multinational corporations. Faced with the general lack of understanding and prior research on how the concept of ‘responsibility’ could best be applied in the context of innovation, the TSB built heavily on the standards for Corporate Social Responsibility (CSR) adopted by large companies, particularly in the financial sector.

The EPSRC has supported a long term initiative that, given its remit as a research council, targets mainly the behaviour of researchers, even though it is generally referred to as a RI initiative. Their AREA approach (Anticipate, Reflect, Engage and Act) has much stronger links to the EU RRI research programme than the TSB initiative. Owen (2012) stresses that “... its departure point is reflection on the purposes and motivations for innovation, anchored in cooperative values, and directed towards ‘the right impacts’. Responsible innovation seeks to ensure that innovation is targeted at and stewarded in real time towards, socially acceptable and desirable ends in the face of uncertainty, in a way that is anticipatory, reflective, deliberative and – ultimately – responsive, coupling reflection

²⁹ Kuhn, T.S., ‘The Structure of Scientific Revolutions’ University of Chicago Press, 1962

³⁰ Kuntz, M. ‘Science and postmodernism: from right-thinking to soft despotism’, Trends in Biotechnology, 2017, TIBTEC 1470 <http://dx.doi.org/10.1016/j.tibtech.2017.02.006> (accessed 5/3/2017)

³¹ EPSRC (2017) *Anticipate, reflect, engage and act (AREA)*, <http://www.epsrc.ac.uk/research/framework/area/>, accessed 3 March 2017

³² Technology Strategy Board (2012) *Responsible Innovation Framework for Commercialisation of Research Findings*: http://webarchive.nationalarchives.gov.uk/20130221185318/www.innovateuk.org/_assets/responsible_innovation.pdf, accessed 12 March 2017

to action and creating opportunities for innovation”³³. The paper by Owen et al. ³⁴ gives a detailed account of the AREA approach.

The PAGIT Responsible Governance Framework combines elements of both the TSB RIF and the EPSRC AREA initiative. It responds to the above perceived inadequacies of current RRI approaches and also the need to integrate RRI more constructively alongside standards, guidelines and regulations within the overall governance of innovative technologies.

3.3 A new approach to responsible governance of innovative technologies

The PAGIT approach to responsible governance builds on this critique of:

- the scale of recent funding directed to a single, narrowly specified paradigm;
- the political biases that it has incorporated; and
- the lack of consideration of the vagaries of the innovation process and of the regulatory constraints that will inevitably limit companies’ capacity to develop new products and services.

The proposed approach attempts to ensure a balance of influence across all relevant stakeholders, to broaden the range of issues on which engagement should focus, to build on governance related initiatives that are already well understood by companies, to identify clearly what is and is not required of companies developing disruptive and/or incremental innovations in different sectors, and to take account of the time constraints and competitive pressures experienced by innovative companies.

4 Project participants’ views on responsible governance and the PAGIT approach

As described in Section 2, interviews and a workshop explored the proposed PAGIT approach to responsible governance of innovative technologies, involving development of standards relevant to RRI including responsible engagement (REng). The materials sent to participants as a basis for discussions were based on the report of the first PAGIT project and the objectives outlined in Section 2. The outcomes of discussions with project participants are summarised under the following headings.

4.1 Engagement processes

4.1.1 When to engage – points of intervention

Many participants agreed that engagement about RI is best undertaken around TRLs 5 and 6 and beyond, when there will be sufficient understanding of the eventual properties and applications of an innovative development and sufficient evidence on which to base discussion or decisions on future development pathways. This timing may also contribute to avoiding unnecessary ideological influence on discussions that could take place around unrealistic, hypothetical future properties of a technology when engagement is undertaken at earlier TRLs.

Upstream engagement at the research stage (RR) was seen as more resource intensive, more risky and difficult to get buy-in from stakeholders. For a meaningful dialogue a participant (consultancy/think tank) proposed having different points of intervention, moderated by different players and this discussion went on to consider:

“... whether it's possible, given the flood of emerging technologies ... to devise a point of entry and engagement when it is at the ... ‘what if’ level. ... [there might be] a cascade of points of intervention and different forms of engagement”,

³³ Owen, R. (2012) From co-operative values to responsible innovation, *Projectics /Proy ctica / Projectique* 2012/2 (No. 11-12), p. 5-12. DOI 10.3917/proj.011.0005.

³⁴ Owen, R., Stilgoe, J., Macnaghten, P., Gorman, M., Fisher, E. and Guston D. (2013) A framework for responsible innovation. In eds. R. Owen, J. Bessant, and M. Heinz, *Responsible Innovation*. John Wiley & Sons.

suggesting that structuring engagement around ‘what-if’ scenarios would lead to better informed early stage public debate and structured conversations.

An alternative point of view was that discussion about RI did need to take place during the early stages of research on an innovative technology:

“... it was important to get the governance right first, so it was governance before deployment, governance before you took the research beyond the lab, and I guess there’s a principle there which one can disagree with or not”.

4.1.2 With whom to engage

In discussing who should be regarded as a stakeholder with a view to being included in a dialogue or consultation:

“We kind of assume that anybody can be a stakeholder if they stake a claim to an interest in that technology, [including members] ... of the public who felt they had had a stake in a particular technology, even if it’s only a moral stake.”

Narrowing this down, the point was made (by a consultancy/think tank representative) that “... citizen representation is not the same as having NGOs (non-governmental organisations) as part of the participative process.” This point was related to a distinction between ‘absolutists and rationalists’ with similar parameters to distinction between interest- and values-based engagement³⁵. This distinction contributed to workshop discussions under several of the following headings.

“... you have to engage with ... the absolutists and the rationalists. ... the problem is not about expertise, who’s entitled to speak or not, it’s a power structure of the people that are participating in the debates. ... for the absolutist it is only a binary option. It’s either yes or no. ... And that absolutist position is defined in very particular and precise ways that actually mitigate against any other sort of option.”

From the point of view of another consultancy/think tank representative:

“... what I see mostly in responsible research and innovation is that this is the science community reaching out to society but still from their own perspective. [On the other hand]... we very explicitly start from the citizens’ perspective. So that means that in theory if there were to be say a conflict between citizens and scientists we would take the citizens’ side. We’re talking about informed citizens so ... not necessarily what they think is good for them but what’s maybe a good solution”.

And from the perspective of a regulator:

“We have a public consultation [but] we struggle very hard to get members of the public to actually contribute to any consultation, although it’s in the public domain.”

The workshop considered whether large companies are better resourced and so able to participate in RRI, the potential for small companies to be shut out of the process due to lack of resources, and then the implied loss of the most innovative voices. From an academic social scientist:

“We did do a workshop with industry ... and a lot of the companies kind of got it and they understand the process, in terms of ... the need to be anticipatory or the need to work with stakeholders to see how others are framing the issue. So there was definitely ... an appreciation of those sorts of dimensions but of course what was coming back was ... if we’re going to invest in this we need to see the return on investment and the value that this is going to bring and not a lot of our venture

³⁵ Tait, J., (2014) Bringing it all Together. In Annual Report of the Government Chief Scientific Adviser, 2014. Innovation: Managing Risk not Avoiding It. Evidence and Case Studies, pp 129-136 (<https://www.gov.uk/government/publications/innovation-managing-risk-not-avoiding-it>)

capitalists are willing to put in more than one per cent on something you're not going to see a return. So they could see it in terms of benefitting the sector as a whole, but individually they found it very difficult to engage with from a resource-based point of view."

4.1.3 How and about what to engage.

Participants raised issues related to the engagement process, the different experiences of engaging with absolutists and rationalists, the need to engage responsibly and the outcomes to be expected.

Questions seen as relevant to engagement processes included: how open-ended the engagement should be and what procedures should be in place to guide engagement to a conclusion or decision; and whether procedures will be different depending on when along the technology pathway the engagement begins? For example, participants pointed out that the more upstream the engagement, the more uncertainty there will be about the future nature of the innovation by the time it reaches market-readiness, constraining the ability to address some of the questions likely to be of greatest interest to stakeholders. A workshop participant commented:

"... to have meaningful dialogue and debate one's got to have some form of certainty. I think this is where we've got a lot of learning to do as a society, is what works at the point of intervention ... around an emergent product or process, ... around a product that is about to be commercialised?"

Several different perspectives emerged around the question of engaging with absolutists (Section 4.1.2). For example:

"... if you seek common ground you can find it with extremists... [but] whether they're political ideologues who then recant after a vote's been taken, or whether it's campaigning NGOs, that's not the way to develop a sustainable society. [The important point is] ... not to let the extremists, ... whether it's an executive or a politician or a campaigner, to distort and tip the debate or the conclusions around their particular extremist perspective. ... Sooner or later a combination of values and common sense and data and expertise congeals to shift positions and change the nature of the debate. And I think this is ... why rigorous engagement is so important." (consultancy/think tank)

"It would be useful to think about having a dialogue that is not about should we or shouldn't we stop this, but more about how can we take this forward? ... It's not an 'if' question it's a how question".

"... it feels like the attack is always ... against the technology. I think it is just as justified to have an attack on the world we have without that technology. ... With the absolutist ... it's a clash of world views. And ... by being open over time the absolutism of the world view becomes apparent ... And for 99 per cent of people it's not convincing. And so a marginalisation happens ... [but] Unfortunately there's a lead time until that happens." (consultancy/think tank)

"... there are a couple of more polarised issues where people actually start investing quite a bit of time to make fake evidence look like real evidence but those are the exceptions." (consultancy/think tank).

The Green community ... establishment has been ... talking this mantra of anti-GMO for so long that they can't step away from it now. It would mean they've been wrong for ... so many decades ... but the young people have a more nuanced view and they're starting to break out and speak up. ... It's a slow process and it will take another decade probably before the youngsters really start getting into positions of power and there's a real actual change also to the public debate and to its recommendations for policy... .

On the question of how to engage responsibly, and about what, the consultancy/ think tank representatives with remits to undertake stakeholder engagement emphasised that you first need to create a mind-set of openness and willingness to listen and that means being open to people's concerns. Also, engagement and transparency were seen as means to shift the debate away from "the scaremongers".

Other comments on the topic of engaging responsibly included the following.

"you also have to be not allowing those absolutists to frame the terms of the debate and that's where I think talking about the nature of the problem that this technology is being designed to address ... and illustrating a world without ... that problem is an important part of engagement with the public."

"citizens ... need to make sure it's their responsibility as well if they want to engage in a debate So we stimulate them to ask for evidence, ... and to not just believe everything that somebody says but to ... check the evidence behind it."

"[Debates should be] ... public led, expert fed and that's the bit where we see things go wrong is when it's expert led. ... because people ... want to be listened to ... it's up to ... the experts to make sure that you know what the concerns are."

Where somebody is very anti-GMO, "... you can usually pin it down to two underlying ideologies ... anti-corporates and ... anti-technology. ... You ... need to stop talking about GMOs ... You need to talk about corporate responsibility and about the world of technology in societies ... If you would acknowledge that there is an issue with corporate responsibility and you discuss that first then afterwards they might be more inclined to listen to the more nuanced story behind GMOs." (consultancy/think tank).

"... the business sector ... [have] been reaching out now to NGOs, to the sustainability community trying to make sure that the term 'the innovation principle' [is] ... more publicly accepted, to show as well that this is something to benefit society and not to benefit business and industry. ... there is a debate to be had there on corporate responsibility, on the role of industry and business in society, on social responsibility of companies".

"One of the main arguments that I would use in the debate on GM, ... [is] that the current regulations are ironically supporting the interest of the large companies. ... usually when I bring that in that's a new idea for most people ... but we're not managing to get that discussion to the public." (consultancy/think tank)

On the questions of the outcomes of a stakeholder dialogue or engagement, the potential need for consensus, and the ability to cope with disagreement, participants emphasised the need for compromise.

"So it's about compromise, yes, because you have to move forward. You have to make a decision at some point but the decisions should always be questionable so one of the main focus areas [should be] accountability. People can make wrong decisions but they should always be accountable for what they've done and ... be able to explain the reasoning behind their decision."

"The purpose [of RRI], I think, is just to open up and provide a sort of guiding framework within which people can operate with no assumption about what the end result is going to be, whether it's going to be stop, start, go faster, go slower. ... It's whether it's in society's interest, ultimately (academic social scientist)."

"Whenever public money or tax money is involved I think we have to aim for as democratic a decision as possible. But I can say when it comes to this participatory approach to decision making, especially in relation to GMOs or gene technology ... a large majority of the public do not actually care." (research scientist, Sweden)

This point was echoed by another UK research scientist: *“from my experience of the UK ... the average member of the public ... does not care. It is almost ironic that there is the perception by the policymakers ... that there is this fear about GM. ... the louder voices that are usually the NGOs, as the representatives of the civic society, ... make the case. But the average person in the street does not care.”*

Concern was expressed over the extent to which the EU framing of RRI dominated the discourse. On the other hand, for an academic social scientist, the EPSRC AREA approach (see Section 3.2) was described as putting emphasis on: public and stakeholder engagement in terms of developing and influencing trajectories; the ‘anticipation’ element which was seen as important to open up the pathways to impact; and the ‘reflection’ element (including first order reflection about our own assumptions and motives and also second order reflection on institutional and political norms. The final dimension, ‘Act’ was seen as in danger of being forgotten.

The same participant pointed to the path dependencies and lock-ins that we face and the tendency to frame innovation as a social good, seeing this as a real constraint on ideal practice. The issues of agenda setting, empowering social agency and technological choices are part of the democratisation of innovation governance, and *“When you move away from risk assessments to more democratising innovation governance, that’s when we start to have real problems in terms of the actual doing of this stuff in practice.”*

4.2 Trust, transparency and evidence

Achieving public trust in innovation and regulatory processes is one of the stated aims of most engagement initiatives and some participants raised the question of the apparent public rejection of experts and expertise as problems for effective RRI. Others did not see evidence of that rejection in practice – *“... there is a principle at stake here, people who do have knowledge about what are correct statements ... [should] pass on that information. Not to tell the public what to think, but ... so that ... public debate takes place, ... on a platform ... provided with good evidence”*.

The knowledge imbalance between experts and public stakeholders was seen to be a key issue for stakeholder engagement initiatives where experts know more about a specific area than the public. Additionally, all stakeholders will tend to emphasise the evidence that supports their point of view, whether based on self-interest and rationality or on a value-based or absolutist point of view. Underlying that distinction, *“... it’s not just the knowledge that you have, it’s the motivation for what is stated”* and that should be part of the evaluation of evidence in an engagement initiative.

Project participants raised concerns about the biases involved in some engagement processes, resulting in inaccurate perceptions that then became obstacles to an effective RI approach. Engagement initiatives were seen by some to give a platform to the loudest voices that do not reflect the concerns or needs of civil society as a whole, leading to exaggeration or distortion of the expected risks and/or benefits of a technology.

Some participants also raised issues of trust and perception as obstacles to achieving an effective RRI approach. Discussions explored how a REng standard might be used to overcome such challenges, centred on the potential for collaborative information sharing and learning between experts, stakeholders and the public, rather than experts informing the public. This form of collaboration would build a more holistic understanding of a technology’s potential and implications and might result in alternative technological pathways or outcomes.

“The collaborative approach ... effectively informs [and] ... provides opportunities for deeper exploration and consideration. It provokes an emotional response so that you can get a sense of people’s values ... [and] enables expression, highlights honest opinions and values and gives very powerful feedback and provides new insights and perspectives.” (consultancy/think tank representative)

Some participants suggested that openness on the uncertainty of the evidence surrounding benefits and hazards of an emerging technology is necessary to create trust between experts, stakeholders and the public and to facilitate buy-in to any future decisions regarding a technology.

“Part of transparency is being able to say, we don't know that yet. But this is what we're doing to answer those questions. And discussing is about recognising what you don't know, as much as sharing what you do know, and listening to others. When you're engaging you shouldn't just give the upside and the optimistic view, you should also give the downside. And in that I would include the knowledge gaps.”

Overall, participants thought that employing a collaborative, transparent approach to engagement would lead to decisions that, while perhaps not universally favoured, would at least be valid to all stakeholders and the public.

Such engagement “might encourage more people to feel confident about being able to engage with specialists, whether they're experts who will also have to be admitting a lot of uncertainty ... there might actually be a value and a cascade of points of intervention and different forms of engagement that conceivably might lead to a better informed public debate.”

“ ... it's all about trust. It's who you believe and who you don't believe, ... and the basis in which society can have confidence in the way that companies and government encourage the birth of these innovative, disruptive, mind-blowing technologies. ... If you're uncertain you have to say you're uncertain. And you've got to trust the public to process this information and make their own minds up. ... the starting point is not ‘we've got to win’ (which is unfortunately the starting point of a whole load of other people, certainly of the NGOs who behave abominably). And they are not held to the same kind of exacting standards that we expect of scientists and regulatory bodies. But ... in the long run journalists for example will start to spot who are the ones with integrity.” (consultancy/think tank)

However, concerns about how to broker a collaborative approach and whether such an approach would produce the best decision regarding an emerging technology remained among some project participants. For example, from an academic social scientist:

“From a corporate point of view, it's really hard to argue for openness and engagement when competitiveness relies on information asymmetry, and that's a real problem in terms of advocating an RI approach when you have to tension that against competitive advantage and protection of intellectual property, set within a context of a competitive knowledge economy.”

4.3 Risks, benefits and regulation

How regulatory systems interact with engagement processes is one of the central concerns of the PAGIT Framework and the following points on this question were raised by project participants.

“Getting people from arm's lengths bodies, regulators, expert advisory committees and so on to speak [publicly], particularly at times of crisis is very, very difficult. It's so tightly controlled ... in the [last] nine years ... we've had one comment from the [regulator] and ... that person got castigated by [a regulatory] press office for ... [speaking] out. ... part of consultation is transparency and visibility ... and I think you lose public trust. ... and so I would just recommend that [regulators] be given more free reign to connect with the public.”
(consultancy/think tank)

(From a regulator's perspective) “It is a controlled engagement. ... You need to make sure that you're not exacerbating a situation or over-stating things. ... But I do take your point, we could definitely be better in terms of communicating and things are changing. ... in terms of what [we] are doing in an outward facing perspective.”

A participant from a research centre commented on the public understanding of regulatory systems:

“we have visitors in our field trials and people are not aware really of the measures and the procedures and biosafety rules that we follow ... It's a revelation to them ... it helps build trust that things are done in a way that it is safe ultimately for the environment, for the people that are working there and so on.”

To overcome the mutual distrust between industry and other stakeholders, project participants proposed that there should be more equitable consideration of risks *and benefits* of innovations in an engagement initiative. Where assessment of a potentially disruptive technology focuses mainly on risks, this can result in distortion of public framing of an emerging technology as was the case for GM developments in the 1990s. Project participants proposed the concept of ‘risk of risk aversion’ where *“... the comparison should be made between the potential harm of allowing this product to be developed and the potential harm of not allowing it to be developed”*. This could then lead to discussion of alternative technologies as a way of contextualising risks and benefits.

Discussions on the future regulation of synthetic biology/gene editing (see PAGIT case study on this subject) advocated including the benefits of innovative technologies alongside any potential hazards in future regulatory systems. However, regulators and other participants involved in those discussions and in the RRI-related discussions reported here expressed the opinion that it would be preferable to engage first with stakeholders on the relative benefits of proposed innovations, alongside risk-related discussions and subsequently to feed that information back into the regulatory process.

Comments from the regulator’s perspective on assessing benefits as part of a regulatory system noted that they tend to look at health and safety statistics:

“We're talking about the ... billions of pounds cost of ill-health to industry. ... not ... the benefits of particular crops that are drought resistant [or] ... the benefits of eradicating malaria in developing countries. So the benefits side is very peculiar to who's actually looking at it. ... it's quite important to try and keep them separate [from the regulatory process] ... otherwise you risk over-complicating it. ... If we have to look at benefits across a whole range of different criteria, ... the potential to hold things up would be quite immense. ... So if I'm looking at this from a health and safety perspective, ... how many GM techniques have caused significant environmental impact? All these questions that you can ask and say well actually, why should we be putting a lot of resource into this area when there are 140 people dying at work every year? So you also have to think about what resources the regulator has to do the things that you'd like it to do.”

From the perspective of an agriculture-related organisation, farmers’ views on the benefits of new breeding techniques were seen as very positive. They are:

“keen to be able to realise the opportunities ... they see the production challenges and the need for increased resilience to climate change related issues and disease and pests and so on, and any kind of technological solutions to that, they are desperate to be able to use [them]. ... certainly with the gene editing stuff they are very concerned that it'll go the same way as GM.”

This view was linked to the reduced number of chemical pesticides available and the possibilities of using biology rather than chemistry, linked to EU regulatory systems for GM and related technologies, seen as blocking their ability to access the technology.

4.4 Politics, science and innovation

Complicating efforts toward a more collaborative approach to engagement, project participants stressed that politics, as opposed to science, tends to dominate discussions and decision making on emerging technologies, particularly in life sciences so that engagement initiatives can further polarise opinions along political or ideological fault lines (Section 3).

On the topic of political influences on decision making, a participant commented on the relationship between the European Food Safety Authority (EFSA) and the EU in dealing with the regulation of GM crops:

“The advice and opinions EFSA give is often scientifically sound. The problem is in the decision making. You can have an opinion from EFSA, but the ... policymakers that form the committees in the EU do not pay sufficient attention to the EFSA advice. So, from a responsible governance perspective and from my own scientific perspective I would say there is an imbalance. The politicians and policymakers, they give a lot more weight to other stakeholders than scientists.” (academic scientist)

Participants argued that, particularly where a debate is polarised, expecting engagement to lead to a consensus is unrealistic.

“... getting a good regulatory system in place is all well and good, but actually it comes very much down to politics, policy and values and opinions.” (academic natural scientist)

“the reason that RRI looks like it does at the [European] Commission level is because the sponsors of it were ‘science in society’ people so it all became about stakeholder engagement, ... So that’s part of the problem. It’s where the money’s coming from and what their agenda is. [The EC] were all about social scientists getting together and thinking thoughts and they didn’t go anywhere because to me ... they were social scientists talking to themselves in the cul-de-sac of knowledge, as I call it, with academic papers that nobody could really understand and websites that were useless. So that was 20 million euros plus not very well spent. ... This is a criticism that I’ve heard from businesses particularly. ... So I’m not sure ... whether [RRI is] necessary, because when you look at the issues that are associated with it they’re all straightforward CSR issues, responsibility, health and safety, stakeholder engagement. We’ve had standards on all that lot for decades.” (consultancy/think tank)

Where debates have become polarised, participants emphasised the amount of time it is likely to take to overcome the political and ideological biases:

“I would like to invite all the different stakeholder groups and the public to consider the entire range of plant breeding techniques and then ...it will take a long time, there will be a lot of distrust and a lot of loud voices, but little by little, maybe people will start to overcome that instinctive fear ... towards recombinant DNA. ... The blight resistant potato, ... it’s ready for the market but it doesn’t get approval in European Union. People need to hear more about that, for example the story can be that you have the European Parliament blocking the adoption of an environmentally friendly potato variety. That could change opinion also. (Academic natural scientist)

Considering advocacy for biotech innovations:

“how [do] we narrow that gap between us and the green NGOs in terms of what farming can deliver that’s not just food ... what we can do is the environmental land management side of farming that no one else can do. And if we can narrow the gap by basically saying, we want the same things but we’ve actually got a practical way of delivering it and it’s based on evidence ... [I] got a mandate to produce a clear statement ... [for] the biotech companies saying, we want your technology, and I didn’t pursue it [because] ... we still have a number of members who are vehemently opposed to the technology. And even though they are a vanishing minority, as a membership organisation we have to acknowledge that ... it continues to be a tricky one.” (agriculture-related organisation)

Reinforcing the perceived political influences on the EU RRI research agenda:

“I try to avoid going too deep into responsible research and innovation because I’m a bit sceptic about the term, frankly. I’ve talked to [EC official] a couple of times, and [the official’s view] ... is that the concept of responsible research and innovation was devised as a kind of a stop gap because [the] new Framework Programme did not contain any social science part to

continue the ELSI ... research in previous Framework Programmes, because the commission wanted to do away with it. And responsible research and innovation was ... an invention to save some of this research funding by linking it to innovation; which is a mantra of the European Commission. And [the EC official] ... just invented a kind of an empty signifier. ... the political agenda [that was] foremost, ... was to find some funding for social science work within research and innovation. The way RRI developed in the European Commission is a tick box [approach] for projects, which I think is totally inappropriate.” (Academic social scientist)

From other participants on the same topic:

“I have heard is that views are very split. A strong vociferous minority that supports RRI, and there are many ... that view it as a nuisance.”

“I see a future role for technology assessment in providing better evidence and keeping up the [quality of] evidence. ... public participation, all those efforts, they’re well intended but they have shown severe problems, both from the sides of the participants because nobody would attend such events any more, and from the side of the results that come out because they are useless in most cases. And from the respondents, I mean the target group, neither politicians nor industry, nor anybody would pay attention.”

4.5 A standards approach to responsible governance

Participants were generally supportive of a standards approach to responsible governance of innovation covering the following points.

4.5.1 Desirable properties of a standards approach

Desirable properties of a standards approach were seen to include:

- the need to avoid making people feel that they were being excluded;
- to ensure the quality of the evidence that people bring to the table to support decision making;
- openness, relating to accountability and to engaging with different types of audiences;
- enabling reflectivity and deliberation;
- standardisation of language

One participant raised the question whether people would be interested in a minimum requirement or in a “gold standard” approach and the response (from a regulator) was:

“It would be minimalist, what is the least you have to do. But this [a standard] isn't regulation. This is actually what do you want to convince the public or going wider that you're doing this responsibly. As a regulator my response would definitely be minimalist.”

4.5.2 Language, terminology and building consensus

Building a common language is an important element of any standards process and is also very relevant to the capacity to achieve consensus. From a standards developer’s point of view:

“I think you have to have language that covers the principal elements of debate. Whether that's to do with values or principles or concepts or whether it's to do with actual different parts of the technology or product that's being developed. [When people are] ... trying to communicate or persuade or even just to explain what they're doing ... terms [have] been misused either carelessly or deliberately by stakeholders who are very active in the debates about what technologies, what products, what processes should be allowed.”

A participant suggested that developing a standards approach to responsible governance is likely to differ from the usual consensus-based approach to standard development. *“What you may want is agreement that some people can go in one direction and other people can go in a different direction and both will be allowed to coexist.”* Linking this to the above discussion on ‘rationalists and absolutists’, a problem for this approach to consensus was that *“ the absolutists want everybody to behave in the same way and want to prevent anybody from doing anything that's different”*. This

was seen as potentially mitigating against a more pluralist approach to standards development, given that “... responsibility is a very value laden term and the absolutists would claim that their right to participate is as justifiable as anybody else's” whether or not they can be persuaded to sign up to a standards based approach. An example given was the divisions between organic and conventional farmers: “... the organic people, they think alike [and] have hindered others to have the right to make a choice.” (agriculture-related organisation)

Following through on the discussion on organic farming, from a consultancy/think tank representative:

“I'm trying to find a way that standards, wherever they are applied improve the common good ... Organic absolutists might be trying to do down every other type of agriculture, ... the absolutist wing, if you like, of the organic movement ... is speaking for the whole industry, ... but is not representative of it.”

Considering the question of how to deal with different kinds of motivation for taking part in an engagement initiative the discussion continued to focus on farming systems:

“ ... we're talking about ... the capacity to have a much greater variety of different kinds of farming systems all competing, all of which are sustainable in one way or another depending on your definition of sustainability. And they could be compatible with one another, except for the fact that different people feel differently about them. And can we get that kind of consensus going in a way that would enable greater variety and presumably also greater resilience and robustness in our food production systems. ... And I think that standards can help do that. But there's got to be give or take.” (agriculture-related organisation)

With an important caveat:

“... don't try and please all the people all the time, ... you'll never placate the extremists, so don't even try. ... engage with them, yeah. But let themselves make it impossible to engage with them. ... something along those lines I think is really important”.

4.5.3 Benefits of standards

Considering the benefits of standards from a consultancy/think tank point of view:

“... [given] the speed and spread of innovation and the ability of society let alone Government to catch up with what's happening. There's the dilemma that's already been mentioned of who benefits, who profits? There's the problem of antiquated, weak and or distrusted and under resourced regulatory and political overseers, as a generalisation about society and its relationship to Government. And there are aggressive companies and campaign opponents and there is public caution and confusion. ... that's the ground against which we have to think about standards and what their place is in helping to rise to those challenges and overcome them.”

The same participant observed:

“... for risk management, for engagement, for creating good judgements based on trust. These are the key points ... [that we] actually can take this complex of innovative technologies which are rushing upon us and to be able to slow them down sufficiently that all the key players, government, industry, academia, society, community actually are most likely to get the best benefits and avoid the worst pitfalls.”

However, the notion of using a standards based approach “to slow things down” was challenged:

“ ... you have to consider what the real world alternative is if we slow this down. How many people die if we slow it down compared to how many could die if we speed it up. ... that is the right way to be thinking, compared to the slow, incremental, automatically precautionary way which can be damaging passively.”

Also, “ ... the application of different types of standards for me would be a way of accelerating the resolution of these conflicts. ... As I understand it, we're trying to see what

role standards of different types play in different ways [and] can help resolve conflict and lead to responsible engagement and better risk assessment.”

Two representatives from agriculture-related organisations commented on the benefits of a standards based approach to stakeholder engagement:

“... we as a stakeholder organisation would sign up to something like that, that adds credibility, and it enables us to get involved in that process ... it’s as much [about] organisations getting funded or questionable activities of organisations. I think this is the problem, that there isn’t anything apart from our outrage to prompt anyone into action, so if there’s actually something available like a standard, I think that would be really valuable.”

“The trick is getting everyone on the same page and getting everyone to sign up to it, ... and you can hold people to account ... having certain organisations on board and saying, look, we support a framework like this, is often a way to get politicians to ... feel that [it] represents a section of society, or a particular interest they think needs representing. ... And ... you will have certain groups almost hold you hostage to say, well, we’re going to pull out unless you have this specific provision or something like that. ... it would be quite hard probably to get some of ... your NGOs with extreme views along, but you might be able to get along maybe consumer groups, or people that represent the food manufacturing ... because they’re a bit more reasonable, a bit more rational.”

An academic social scientist, while recognising the benefits of a standards approach, had concerns about how to deal with the outcomes of a standards approach to engagement:

“I think a standard that says you should think about these kinds of approaches, and then if you do those, you’re doing an RRI and you could standardise that, then yes, you’re meeting the standard, it’s a useful and valuable thing, but the point is that the outcome should not be part of that. In other words, there’s no implicit assumption that it’s going to end in banning a technology or banning research. In fact, ... in some cases it might be in society’s interest to take risks and push things forward a lot more quickly.”

4.5.4 Role for a Corporate Social Responsibility Standard.

A government policy adviser from the Netherlands noted:

“... the way ... we deal with it [RRI] is just to ignore the term. ... you can implement everything that falls under the heading of operationalising responsible research and innovation without using the notion of responsible research and innovation. ... talking to the companies we try to explain it in terms of CSR for research. ... And that works because they know what CSR is, ... the basic strategy is to align with the values of the companies that we’re working with and ... starting from those values, starting from real life problems that deserve a solution you can do a lot of things that fit all [RRI] goals.”

And from a standards developer:

“... if you look at any big corporation today ... [CSR] initiatives ... have senior level support within companies, and that makes it an attractive thing to consider from my point of view.”

On the other hand, considering the process of incorporating CSR within an overall approach to responsible governance:

“... the way that most NGOs use CSR is that it’s something to do with the 1990s, and is an antiquated and shallow term ... I wouldn’t have thought that other stakeholders would immediately feel comfortable with using CSR as an umbrella approach. NGOs in particular, ... probably academics as well, especially those who work on NGO type agendas.”
“I think most of our academics wouldn’t want to be associated with a term that has the word corporate in it.” (academic social scientist)

“In certain communities CSR is understood to mean something that is pretty out of date, pretty weak ... whether it's because it's corporate or in some way it's not adequate these days with the sustainable development goals (consultancy/think tank).

4.6 Summary of the main issues raised in discussions with participants

4.6.1 Engagement processes

The dilemma entailed in engaging with “absolutists” was a consistent concern for participants, with a consensus on not allowing absolutists to gain control of the dialogue and to determine citizens’ framing of the technology. Equally they should not be excluded from dialogue. There was less agreement on how that could be done, and how quickly entrenched stakeholder perceptions based on inaccurate evidence could be changed, whether it needed to be a long slow process of attrition of absolutists’ influence through continued engagement or could be a more proactive approach.

Particularly relevant in upstream engagement, agenda-setting was seen as potentially politically motivated and therefore problematic, e.g. framing innovation *per se* as a social good. Participants proposed shifting dialogue away from absolutists’ irreconcilable views on a technology to questions of ‘how to take it forward’, and also moving away from a focus on the technology itself towards promotion of responsible behaviour by companies. Lack of ability to achieve a compromise in a dialogue dominated by absolutists’ views, along with the general lack of interest in these questions by the majority of citizens were seen as ongoing challenges.

The need for different points of intervention along the development process, led by different actors, involving different sets of stakeholders and different agendas was emphasised, the most obvious differentiation being between upstream RR at TRLs 1 – 3, and downstream RI at later TRLs.

One participant’s view on the need to ‘get the governance right’ before taking research beyond the laboratory may be widely held among academic researchers and other stakeholders, requiring a proactive approach to explaining the governance approach proposed in the overall PAGIT Framework.

4.6.2 Trust, transparency and evidence

Trust in regulatory systems was seen as an essential component of public acceptance of innovative technologies, underlining the importance of including responsible governance within the PAGIT Framework. The suggestion that citizens now reject the authority of experts was not endorsed by most participants, but they did recognise that stakeholders will tend to promote evidence that supports their point of view leading to a need to understand stakeholder motivations when evaluating the quality of such evidence.

Considering how engagement ought to be conducted, participants referred to: transparency and openness as a means to generate trust among stakeholders; collaborative information sharing and learning between experts, stakeholders and the public; acknowledging uncertainty; disparity in knowledge between experts and the public; the need for high quality evidence as a basis for dialogue; and trust in information sources. These were all elements designed to counter the biases that have been part of some engagement initiatives which have given a platform to the loudest voices allowing exaggeration of risks and/or benefits.

The majority of participants had experience in upstream engagement with public stakeholders and these comments are therefore most relevant to engagement on RR at TRLs 1-3. However, some participants also recognised the tension between openness and engagement and company competitive advantage and protection of intellectual property, requiring a different approach to the conduct of engagement at later TRLs, as discussed in Section 5.

4.6.3 Risks, benefits and regulation

There was strong emphasis on the need for equitable consideration of the benefits of an innovative technology, including the risks of not developing it, alongside any hazards to health or the

environment. An unjustified focus only on risks was seen as part of the process of distortion of public framing of a technology. Participants also agreed that this should be part of the responsible governance of innovation delivered through engagement initiatives and not the responsibility of regulators.

Participants observed that citizens and public stakeholders had almost no understanding of the process of innovation within a company, and the hurdles that will be faced by innovative products, severely limiting the number of innovations discussed at TRLs 1 – 3 that actually reach a market. They were also largely ignorant of the biggest hurdle of all – the regulatory systems faced by most innovations, in life science-related areas at least. Giving stakeholders a better understanding of these issues should therefore be an important part of an engagement standard leading to improved public understanding of the regulatory systems that will influence the direction, timing and sectoral location of future innovative developments.

4.6.4 Politics, science and innovation

If ideological motivations underlying a dialogue are not specifically recognised and balanced by alternative perspectives, this was expected to lead to exacerbation of conflict and politically dominated decisions on risk management and regulation. Such polarisation of views leads to the entrenched stakeholder positions based on inaccurate evidence that are expected by some to take a very long time to be revised.

Under this heading there were strong negative comments on the EU RRI approach, questioning its usefulness, particularly in the RI context, and also questioning whether it will continue to be a part of future EU Framework research programmes.

4.6.5 A standards approach to responsible governance

There was strong support for a standards-based approach to responsible governance, but not for a “gold standard” type of approach that goes beyond what is needed to convince stakeholders that you are behaving responsibly. Standards developers emphasise the need for a common language and participants observed that this is important given the tendency to misuse language as part of the process of gaining political influence on a dialogue.

The approach to generating consensus around a governance-related standard was recognised as potentially different from the usual consensus around a single standard to be adhered to by all. The ideal outcome might be an agreement to allow several different standards to co-exist, for example related to organic and conventional agriculture, this being a basis for resolution of conflict, and also of introducing robustness and resilience into farming systems. However again this would be challenged by the agenda of absolutists whose defining characteristic is unwillingness to consider such co-existence.

Reflecting an earlier divergence of opinion among participants (see 4.6.1), some saw development of a standards approach as a welcome opportunity to slow down innovation while others saw it as needed in order to accelerate innovation processes and avoid losing the opportunity to realise the benefits.

There were also divergent opinions on the value of a CSR-type standard as part of a responsible governance approach. Some participants felt strongly that it would be unacceptable to many academics and NGOs because of its ‘corporate’ emphasis. This is more likely to be an issue for upstream engagement but is something that the responsible governance approach proposed here will address.

5. The PAGIT responsible governance approach

5.1 Overall approach

The approach proposes the development of aspirational, consensus standards³⁶ with the aims:

- to be demonstrably fair to all parties;
- to generate trust in the governance process for all stakeholders involved;
- to build on procedures that are already familiar to many companies, such as compliance with a Corporate Social Responsibility Standard or using a risk assessment matrix as part of conventional project management;
- to be cost-effective; and
- to avoid *unnecessary* delays in the development of innovative technologies.

It focuses on the policy and political structures and procedures that influence decisions about which technologies are developed and when and how they should be regulated, particularly arrangements to ensure that research and innovation development are undertaken responsibly. The Phase 1 PAGIT project³⁷ concluded that this field is open to a new approach to responsible governance of innovative technologies that uses standards to support responsible behavior of *all* stakeholders, including scientists/innovators, regulators/policy makers and citizens/stakeholders.

As shown in Figure 2, a departure from conventional thinking is our proposal that the extent to which an innovation is disruptive or incremental should play an important role in decisions on its responsible governance. Demands for a responsible approach to research and innovation are most often invoked for developments that are regarded as disruptive. Incremental innovations do not give rise to societal demands that they should be scrutinised in this way. For an incremental innovation, there may therefore be no need for additional engagement or standards-related initiatives, beyond compliance with a Corporate RI Standard.

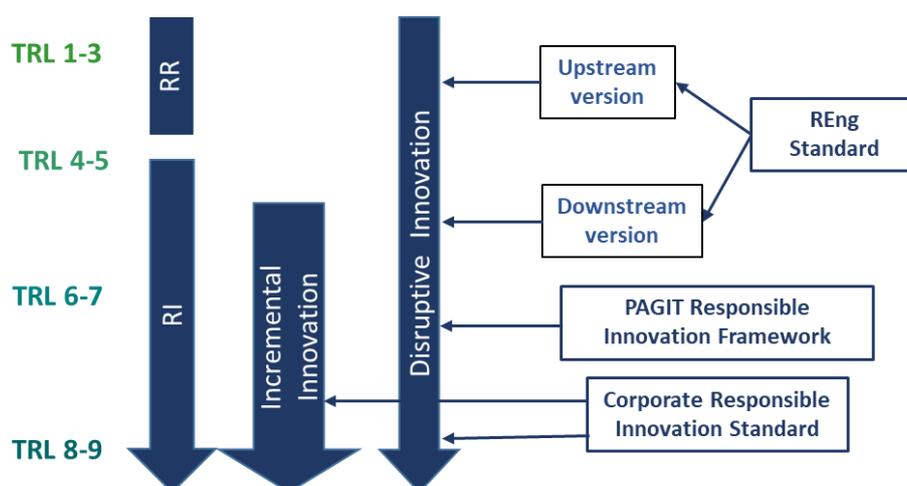
In some cases, societal concerns will be transferred to a potentially incremental innovation from advocacy campaigns related to negative experiences with previous, more disruptive technologies, for example synthetic biology and gene editing and their links to earlier GM crop technologies. This is a reason to treat such cases as if they were disruptive.

In current approaches to responsible governance, regulators, policy makers, scientists and industry are encouraged to decide on the regulatory system for an innovative technology at upstream stages of its development, before the nature of its benefits and risks are evident or are supported by data. Such decisions, made at upstream stages in the innovation process (TRLs 1 – 3), will then influence the direction and rate of development of the technology and also stakeholder framing of its risks and benefits and of its perceived responsibility. Given the evidence of human fallibility in predicting futures beyond 3 – 5 years, we should be cautious about any claims made for this form of anticipatory governance and also careful about the role assigned to RRI in determining the future direction of technological innovation. Thus, a premature upstream choice of regulatory system can lead to inappropriate framing of the technology and of engagement and dialogue, in addition to the other defects of such a decision. Ideally there should be parallel consideration of pre-regulatory standards and guidelines alongside upstream engagement initiatives, both leading into the decision at TRLs 4 – 5 on how the technology should be regulated.

³⁶ Steedman, S. (2013) *Standards and synthetic biology: structuring knowledge to accelerate innovation*. EU Workshop in Synthetic Biology, 11 Oct., 2013. (<https://connect.innovateuk.org/documents/2826135/9165366/7+Scott+Steedman.pdf/763762eb-c49d-4436-8b28-69bdd03637e9;jsessionid=2B0AC4A4659678575BB695F6A164EB3F.2>).

³⁷ 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>)

Figure 2. Standards-based approach to responsible governance



The PAGIT approach to responsible governance (Box 1) is intended to give greater clarity to researchers and innovators on what needs to be done to demonstrate responsibility, for either disruptive or incremental innovation, at what point in innovation processes. For incremental innovation, which will be the majority of cases, compliance with a Corporate RI Standard would generally be all that is necessary. This contributes to meeting the innovation, adaptation and proportionality principles embedded in the PAGIT Framework and provides the clarity needed to enable a company to understand (i) what is (and is not) required of them at different stages in the development process and (ii) how to record the outcomes of their responsible governance approach in a way that meets societal expectations.

5.2 A Responsible Engagement Standard for disruptive and related innovation

Previous proposals that standards should be developed for responsible engagement include: (i) an initiative involving 128 companies developing a standard for responsible corporate engagement in climate policy³⁸; and (ii) an EU funded project³⁹ that has proposed the development of standards for RRI, with a preference for voluntary standards, but including also a proposal for formal, legally binding EU Directives and Regulations, an approach that would be considered disproportionate by PAGIT criteria. These, and many other similar initiatives follow a common pattern: they consider only the need for scientists and innovators to behave responsibly, focus only on engagement initiatives, and make no reference to the responsibilities of other participants in engagement processes.

Discussions with participants in this project reinforced the case for developing REng standards applicable to all stakeholders involved in an engagement. One justification for such standards that came up frequently was the problem of dealing with ‘absolutists’, as contrasted with ‘rationalists’. This dichotomy has previously been described in terms of interests-based (rationalist) and ideology-

³⁸ <https://www.cdp.net/en/campaigns/commit-to-action/responsible-corporate-engagement>

³⁹Expert Group on the State of the Art in Europe on Responsible Research and Innovation (2013) *Options for Strengthening Responsible Research and Innovation*. EC Directorate General for Research and Innovation, EUR25766EN, pp 34-36. https://ec.europa.eu/research/science-society/document_library/pdf_06/options-for-strengthening_en.pdf, accessed 7/6/17.

based (absolutist) engagement^{40 41 42}, with the properties described in Table 1. For this report we will use the interests/ideology terminology. Table 1 was developed with the intention of providing criteria to enable the organisers of a dialogue to understand whether participants are approaching it primarily from an interest-based perspective or from an ideological perspective, and therefore to support more productive dialogue. The Guidelines proposed in Box 2 have a similar intent.

Box 1. The PAGIT approach to responsible governance

1. For **disruptive innovation** or where an incremental innovation is likely to be publicly contentious -
 - (i) A **Responsible Engagement (REng) Standard** tailored to different points of intervention:
 - Upstream, at TRLs 1 – 3, relevant to the conduct of basic research (RR);
 - Downstream, at TRLs 4 – 9, relevant to the development of specific innovations by companies (RI).
 - (ii) The **PAGIT RI Framework**, building on the outcomes of responsibly conducted engagement initiatives, providing a standardised means to track the expected impacts of innovations and related stakeholder responses.
2. For both **disruptive and incremental innovations** beyond TRL4, a **Corporate RI Standard**, based on the CSR Standard, adapted to include aspects specific to innovation processes.

Past experience of engagement initiatives where involvement of ideologically motivated advocacy groups has been allowed to frame a new technology negatively in the minds of citizens, is one reason for lack of trust by scientists and industry in RRI processes. On the other hand interest-based advocacy by industry representatives underlies some citizen reluctance to see companies involved in RRI related initiatives on an equal basis to other stakeholders. The staged approach to the development of REng standards could contribute to achieving a workable consensus on the development of future innovative technologies and many project participants were willing to sign up to future involvement in such an approach.

As noted above, for disruptive innovation or where incremental innovation is likely to be publicly contentious, a REng standard would have different requirements at different points of intervention, between RR (Upstream) and RI (Downstream). The guidelines in Box 2 will be relevant to both upstream and downstream stages with some variation in emphasis between the two.

⁴⁰ 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

⁴¹ Tait, J. (2009) 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.
(<http://www.nature.com/embor/journal/v10/n1s/pdf/embor2009138.pdf>)

⁴² Tait, J., (2014) Bringing it all Together. In *Annual Report of the Government Chief Scientific Adviser, 2014. Innovation: Managing Risk not Avoiding It*. Evidence and Case Studies, pp 129-136
(<https://www.gov.uk/government/publications/innovation-managing-risk-not-avoiding-it>)

Table 1. Properties of interest-based and ideology-based engagement

Interest based engagement		Ideology based engagement
Restricted to specific developments	Uncommitted members of the public >60%	Spreads across related and sometimes unrelated developments
Location specific, locally organised		Organised nationally or inter-nationally
Can usually be resolved by <ul style="list-style-type: none"> • providing information • giving compensation • negotiation 		Very difficult to resolve <ul style="list-style-type: none"> • information is treated as propaganda • compensation is seen as bribery • negotiation is seen as betrayal
Giving concessions leads to mutual accommodation		Giving concessions leads to escalation of demands
Negative events lead to adjustments in products and processes		Response to negative events is disproportionate
Protagonists do not have a higher level cause/agenda		Protagonists look to recruit supporters to a higher level cause

5.2.1 Upstream REng Standard (TRLs 1 – 3).

The RR stages are characterised by the greatest level of uncertainty about the future nature of the innovation itself and even whether it is technically feasible, the resulting benefits and hazards, the industry sector that will develop it and the markets it will create or serve. It will also be difficult to engage with citizens in a way that will be meaningful to their daily lives. This uncertainty leads to greater opportunities for either ideology- or interest-based manipulation of the available evidence, the use by some stakeholders of badly-designed experiments to create ‘evidence’ that does not meet expected quality standards, or the amplification of the degree of uncertainty attached to future outcomes and the unrealistic over-emphasis of future hazards or benefits. Upstream engagement can therefore have a formative influence on the public framing of an innovative technology, particularly one that is disruptive, and this framing can then persist throughout later development stages and beyond, long after most of the earlier uncertainties have been resolved.

These factors underlie the focus on the quality of the evidence used in dialogue in engagement initiatives and Table 1 highlights key differences in the nature of the dialogue that emerges when engagement is ideology-based rather than interest-based. An important part of a successfully conducted engagement initiative will be to understand the interest- and ideology-based biases among the various participants, and to tailor the dialogue to take account of these. For example project participants frequently referred to the intransigence and unwillingness to compromise among those who are engaging from an ideological perspective compared to those who are engaging from an interest-related perspective. The proposed REng standard would help to counteract the perceived political biases inherent in many RRI-related engagement initiatives.

Well balanced, authoritative upstream stakeholder engagement is expensive and difficult to conduct on a clearly unbiased basis and they should preferably be undertaken by publicly funded impartial professional bodies, not by individual companies or academic researchers or any other body that could have a vested interest in the outcome. They should include all relevant stakeholders and ensure that the innovation and its potential benefits, risks and uncertainties are understood by all.

The outcome of an engagement initiative should only be allowed to delay or stop development of an innovative technology under very special circumstances, to be decided as part of the development of the REng standard, requiring careful management of stakeholder expectations.

The outcomes of upstream engagement will be an important input to specifying the 'elements' of the PAGIT RI Framework in the downstream stages of development of the innovation (Table 2).

One participant's view on the need to 'get the governance right' before taking research beyond the laboratory may be widely held among academic researchers and other stakeholders. This challenges the regulatory principle of the PAGIT Framework that it is not appropriate to make decisions about future regulation of an innovative technology at the upstream stages of its development. The outcomes of upstream engagement should not be used to delay or limit the future development of a technology. Instead they should be used to focus future information gathering on specific aspects of the technology as it moves through its later development phases with a view to informing future decision making on technology development or regulatory requirements. This will require careful management of stakeholder expectations about the outcome of a dialogue and a pro-active approach to explaining how it will interact with regulatory and innovation processes (Box 2).

5.2.2 Downstream REng Standard (TRLs 4 – 9)

Beyond TRL 4, there will be less uncertainty about potential benefits, hazards and future innovation trajectories. There will also be a broader range of stakeholders willing to engage with issues which they will see as having some relevance to their lives. Compared to upstream engagement, this stage will probably involve different stakeholders, discuss different types of issues and be able to come to more concrete conclusions on the development of innovative technologies. Companies may be expected to consider the properties of the innovation itself, its potential risks and benefits and their societal distribution.

Downstream engagement will be addressed through the PAGIT RI Framework (Table 2), the 'Engagement' component under 'Organisational Responses'. As noted above, the societal, environmental and health-related elements in Table 2 should be informed by the outcomes of any upstream engagement previously undertaken. Engagement at this stage will involve mainly stakeholders with an interest in the new technology, using the engagement outcomes to inform innovation decisions (the 'Act' component under 'Organisational Responses'). This framework will support innovators in demonstrating responsible behaviour throughout the downstream development of an innovation, including the extent to which it will fulfil the aspirations of citizens, as markets for, or users of, the product.

Development of the standards will include agreed criteria by which companies and external observers can be reassured that innovation is being conducted responsibly at the relevant TRL stage of innovation. Compliance with the proposed standards should be seen as giving companies an aspirational advantage over competitors, should be achievable on a timescale that will not diminish their commercial competitive advantage, and be compatible with intellectual property protection.

5.3 PAGIT RI Framework

For disruptive innovation, and for incremental innovations that become the subject of public or stakeholder interest, from TRLs 4 and beyond companies should monitor their development on a case-by-case basis to cover societal benefits or risks and environmental and health benefits, in addition to the health or environmental risks that will be covered by existing or new regulatory initiatives. The proposed framework draws on the published paper on the development of a responsible innovation approach⁴³, accommodating it to the context of the PAGIT Framework

⁴³ Tait, J. (2017) From Responsible Research (RR) to Responsible Innovation (RI): challenges in implementation. *Engineering Biology*. doi: 10.1049/enb.2017.0010

(Figures 1 and 2). It is designed to be simple and feasible for a company to adopt, considering the cost and timescale pressures on innovators operating in a commercial environment. As described in Section 3.2, it incorporates elements of the RI Framework developed by UK TSB⁴⁴ (now Innovate UK) with the EPSRC AREA approach⁴⁵ (Table 2):

- **Anticipate** – describing/analysing potential impacts relevant to the project
- **Reflect** – on purposes of, motivations for and potential implications of the project and associated uncertainties
- **Engage** – opening up visions, impacts and questioning to broader deliberation and dialogue
- **Act** – using the above processes to influence the direction and trajectory of the innovation

Box 2. Guidelines for the development of a REng Standard

1. Ensure equitable treatment across all stakeholders: discussions should be open and accommodate the full range of relevant opinions; and no single perspective should dominate other opinions or dictate the terms of engagement.
2. As part of a staged approach to RRI, specific aspects of the engagement should be tailored to the relevant point of intervention to consider: who should be involved; which topics are relevant to be addressed; whether and how the outcomes should be implemented.
3. 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.
4. Accept that consensus may not be attainable and manage expectations accordingly.
5. Include in the dialogue the nature of innovation processes for translation of scientific discoveries to products in a market place, the relevant regulatory systems, and the constraints they will impose on innovation outcomes.
6. Ensure a balanced consideration of benefits and risks associated with innovative technologies.
7. Do not allow the values and interests of one stakeholder group to restrict the freedom of choice of others.
8. Include standards for the quality and breadth of evidence that is considered as a basis for decision making.
9. Where there are conflicting values and interests, be equitably sceptical about the impartiality of evidence presented in support of a case.
10. Where there is conflicting evidence, consider carefully the expertise of those promoting the evidence, including both scientific and experiential expertise, and weight it accordingly.

⁴⁴ Technology Strategy Board (2012) *Responsible Innovation Framework for Commercialisation of Research Findings*:

http://webarchive.nationalarchives.gov.uk/20130221185318/www.innovateuk.org/_assets/responsible_innovation.pdf, accessed 12 March 2017

⁴⁵ EPSRC (2017) *Anticipate, reflect, engage and act (AREA)*,

<http://www.epsrc.ac.uk/research/framework/area/>, accessed 3 March 2017

The ‘Elements of RI’ in Table 2 cover properties of the innovation (benefits or risks) that are of interest to stakeholders and to the company concerned, identified through an engagement initiative at or before TRL4, based on the REng Standard (upstream version). The second column will be used to record any variations or new issues as they arise during development of the innovation. The business practice element in Table 2 covers the need to monitor responsible behaviour of any collaborating companies or organisations involved in development of the innovation, not the behaviour of the lead company which would be covered by the Corporate RI standard itself.

The Organisational Responses relate to the conduct of REng at downstream stages of development of the innovation (Anticipate, Reflect, Engage), probably conducted with a small group of stakeholders with a direct interest in the development, the final column ‘Act’ being used to record the outcomes of the engagement and the actions taken. The extent of engagement required should be proportionate to the scale and importance of the innovation concerned and a major disruptive innovation may justify having a dedicated stakeholder panel appointed for the duration of its development.

This approach will be familiar to any company that uses a risk assessment matrix as part of its routine project management, and updating the Framework on a regular basis should be more than a box-ticking exercise. Progress of the development should be monitored regularly on the basis of these criteria so that the RI Framework becomes a living document that evolves throughout the various stages of development of the innovation.

Table 2. PAGIT RI Framework

Elements of RI	Issues arising during the project	Organisation Responses			
		Anticipate	Reflect	Engage	Act
Societal Elements (positive and negative)					
Environmental Elements (risks and benefits)					
Health-related elements (risks and benefits)					
Business Practice Element					
Regulatory Elements					

5.4 Corporate RI Standard

The proposed Corporate RI Standard is relevant to all companies developing innovative technologies, both incremental and disruptive, at downstream stages of development, beyond ‘proof of concept’. It will build on the International Standards Organisation (ISO) Standard for Corporate Social Responsibility (CSR) (ISO 26000)⁴⁶ and also learn from other such standards that have already been developed.

⁴⁶ <https://www.iso.org/iso-26000-social-responsibility.html>

Some participants questioned whether the concept of RRI was either necessary or useful and whether it would be a long term feature of future decision making on innovative technologies. Even if this is the case, it is likely to be replaced by an alternative approach and the PAGIT approach to responsible governance could contribute to such future agendas.

One project participant suggested that a CSR-related standard could deliver everything that was needed in this area and was already well understood by companies, so its adoption would be a quick and effective way to meet at least some of the requirements of a responsible governance approach. As we propose here, that is indeed the case for most incremental innovation, but would not be sufficient to meet the societal and regulatory challenges raised by some disruptive innovations.

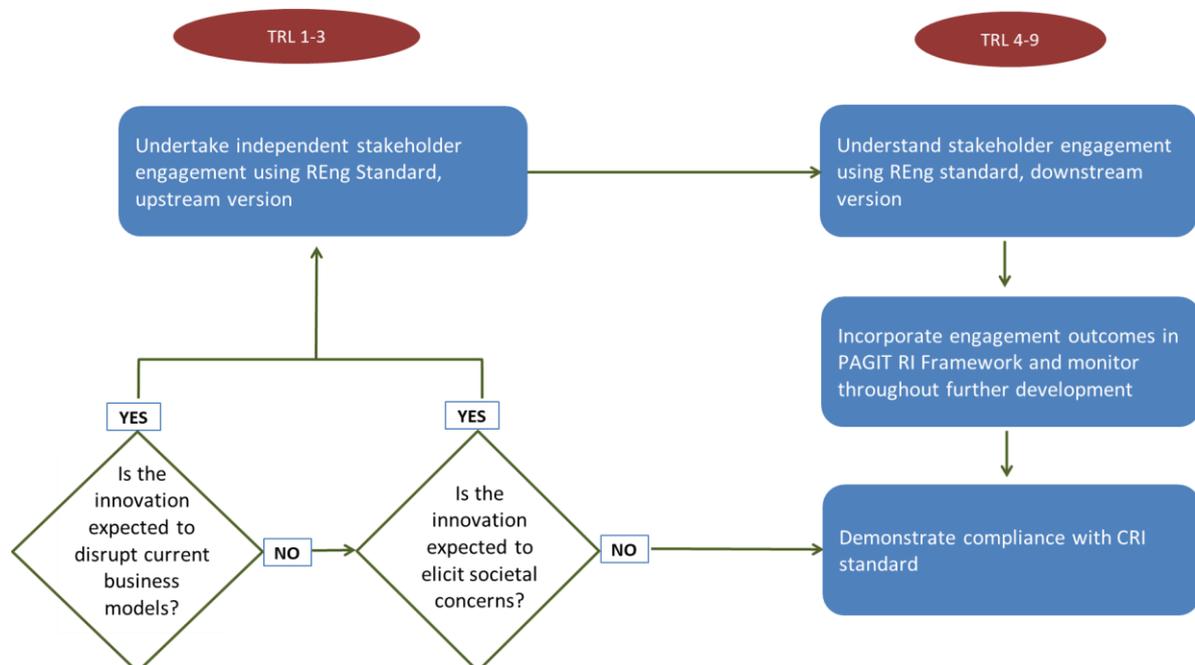
Other participants saw difficulty in persuading advocacy groups and academics to take part in an initiative with ‘corporate’ in the title. This type of concern is potentially an indicator of an ideological underpinning to an agreement to engage and, beyond TRL 4, ideologically-based perspectives are likely to be less central to discussions. For these reasons we believe that a Corporate RI Standard would be a very useful component of the responsible governance approach for all innovative technologies beyond TRL 4.

5.5 Implementing the PAGIT responsible governance approach

5.5.1 Upstream (TRLs 1 – 3)

Figure 3 shows that, for an innovation at the upstream, research stages of development, the starting point for decision making should be to consider the extent to which an innovation is disruptive of existing business models and then whether it is likely to elicit societal concerns for some other reason. If the answer to either of these questions is ‘Yes’, a body with the relevant authority (not companies or researchers), should undertake stakeholder engagement based on the REng Standard (upstream version).

Figure 3. Using the PAGIT responsible governance approach



5.5.2 Downstream (TRLs 4-9)

If the answer to the questions in Figure 3 is 'No', at downstream TRLs 4 – 9, compliance with the Corporate RI Standard, implemented through the company's standard operating procedures, should be sufficient in most cases to meet the responsible governance requirement, in keeping with the principle of proportionality.

Where an innovation is expected to have important elements of disruption at some points in relevant value chains, following from an upstream engagement initiative, companies should:

- (i) As built into the RI Framework, undertake stakeholder engagement (downstream version) and take any necessary actions;
- (ii) Monitor the staged development of the innovation using criteria ('elements') derived from an upstream engagement initiative, using the PAGIT RI Framework (Table 2);
- (iii) Demonstrate compliance with the Corporate RI Standard.

This approach should take account of the extent to which disruptive innovation can experience major changes in properties and outcomes, including emergence of new benefits and hazards or removal of expected benefits or hazards, during the later stages of its development.

6. Recommendations for future developments

6.1 BSI or recognised standards body

Consider development of a set of standards, under the heading 'Corporate Governance of Innovative Technologies', building on the analysis in this report, including:

- REng Standard, upstream and downstream versions and the Guidelines in Box 2.
- A standardised RI Framework
- A Corporate RI Standard

Given that the RRI agenda might be nearing the end of its active life, the PAGIT responsible governance approach could potentially fill the vacuum that will be left in this area, helping to ensure that any future developments take a more proportionate and adaptive approach to encouraging innovation that is safe, effective and meets the expectations of citizens.

6.2 UK Research Funders

Consider the need to undertake engagement initiatives, based on a REng Standard (upstream version), where funded research is likely to give rise to disruptive innovation, or to incremental applications that are likely to be societally contentious. The organisation of such an initiative should be undertaken by an independent public body and/or a commercial market and opinion research specialist, avoiding involvement, other than as stakeholders, of academic researchers with career-related interests, commercial companies with financial interests, or any organisations with advocacy/ideological interests in outcomes.

6.3 Innovate UK

Beyond TRL 4, consider involvement of companies applying for innovation-related translational funding in adoption of the overall standards approach to responsible governance:

- For incremental innovation, based on adoption of the Corporate RI Standard;
- For disruptive innovation and for innovations likely to be publicly contentious, based on (i) as appropriate the REng Standard (downstream version); (ii) the PAGIT RI Framework; and (iii) adoption of the Corporate RI Standard.

6.4 Companies

At TRLs 1 – 3, where a stakeholder engagement is being undertaken by an independent body, take part as one of the key stakeholders whose interests need to be considered.

Beyond TRL 4, consider adopting the requirements of the PAGIT responsible governance approach as part of the standard operating procedures of the company, including all three standards-based components: (i) as appropriate the REng Standard (downstream version); (ii) the PAGIT RI Framework; and (iii) adoption of the Corporate RI Standard.

Annex 1

PROPORTIONATE AND ADAPTIVE GOVERNANCE OF INNOVATIVE TECHNOLOGIES (PAGIT) BSI PROJECT, PHASE 2: PROJECT OUTLINE

Joyce Tait, Geoff Banda and Andrew Watkins, 6/12/16

Advanced innovative technologies will drive future economic prosperity, supporting the bioeconomy and the circular economy, with funding from public and commercial sources. However, the choice of regulatory systems to be applied to these technologies will be crucial in determining the success of industry sectors and even of national economies. Phase 1 of the PAGIT project¹ developed a framework to demonstrate future roles for standards in enabling EU regulatory systems to be more proportionate and adaptive to the needs of innovative technologies. The aim is **to make regulation smarter** in order to deliver more societal benefits from basic scientific research without jeopardising safety, quality and efficacy.

This Framework (see attached case study description) includes consideration of **the extent to which an innovation is disruptive or incremental** in making decisions on how it should be regulated. Where an innovation is potentially **disruptive**, all stages of the regulatory system from early development through to market delivery will need to be considered, including the choice of regulatory precedent on which to base future regulation. For an **incremental** innovation with a clearly defined role in an existing development pipeline, the challenge will be to adapt current regulations, guidelines and standards to the requirements of the innovative development.

PAGIT Phase 2 will expand and refine the specification of the Framework and demonstrate its application in three case studies where the UK can provide leadership on the governance of innovative technologies: (i) **synthetic biology**, including gene editing, (ii) active implantable medical devices (**AIMDs**) and (iii) responsible research and innovation (**RRI**). This initiative is closely aligned to the Government's aim to simplify regulation for UK businesses, and ensure that UK regulators drive innovation and **make the UK the regulatory test-bed capital of Europe**.

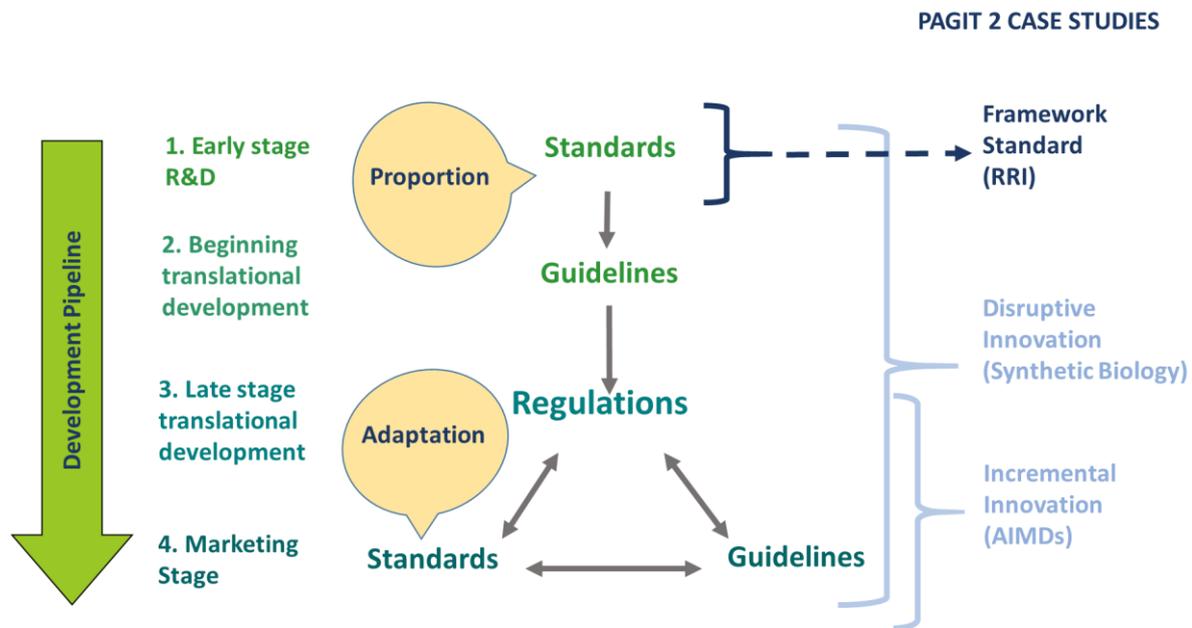
In the context of **the Brexit decision**, the UK economy will generally be best served by adopting regulations and standards that are similar to those of the EU, to ensure continuing access to markets such as diagnostic tools. Even in such cases there will be some opportunities to adapt UK regulatory regimes to be more proportionate to the needs of innovative technologies, and standards could play an important role in this process. Perhaps the most significant opportunity is in the area of genetic modification (GM), synthetic biology and gene editing, where the EU regulatory system has so far inhibited the development of markets. Here the UK could gain competitive advantage by developing new regulations that are closer to those of the USA or Canada and this could enable the UK to become a future location of first choice for companies investing in these areas of the bioeconomy.

¹<http://www.bsigroup.com/research-pagit-uk>

Annex 2

PAGIT PHASE 2 CASE STUDY – RESPONSIBLE RESEARCH AND INNOVATION (RRI): A FRAMEWORK STANDARD

The need for a responsible approach to research and innovation is most often raised for innovations that are regarded as disruptive, particularly where they challenge existing business models at all stages of the development pipeline. In the context of the PAGIT Project the question of standards for responsibility should therefore begin to be addressed, as shown in the figure below, during the early stages of R&D, continuing during subsequent innovation developmental stages.



Current approaches to RRI emphasise stakeholder engagement as the key requirement to deliver 'responsibility'. However, Phase 1 of the PAGIT project⁴⁷ made the case for the BSI to support the development of an aspirational standards approach to RRI that also includes standards for responsible behaviour by regulators/policy makers and by other stakeholders and citizens, covering all stages in the development pipeline. This case study will build on the BSI's experience in the development of consensus standards, in this case taking account of the expectations and needs of a broad range of actors, including regulators, policy makers and citizens/stakeholders.

The project will first engage, through telephone interviews and workshops, with key players in industry, regulatory and stakeholder communities, including those involved in the other two case studies, particularly synthetic biology. The objective will be to identify where and how aspirational, consensus standards could contribute to the equitable acceptance of responsibility across all key players in the governance of innovative technologies.

Outputs will include:

- (i) guidelines for action by industry, regulators/policy makers and citizens/stakeholders; and
- (ii) a future roadmap for a BSI initiative to develop a set of aspirational, consensus standards to deliver 'responsibility' in the development of innovative technologies.

⁴⁷ <http://www.bsigroup.com/research-pagit-uk>

Annex 3

BSI PROJECT ON PROPORTIONATE AND ADAPTIVE GOVERNANCE OF INNOVATIVE TECHNOLOGIES (PAGIT). RESPONSIBLE RESEARCH AND INNOVATION (RRI) – QUESTIONS FOR DISCUSSION.

Joyce Tait, Geoff Banda and Andrew Watkins, 2/1/2017

We would like to involve you in an open-ended discussion about the future governance of advanced innovative technologies and the concept of responsible research and (particularly) innovation as it will apply to these technologies.

The following questions are a guide to the issues we would like to consider, alongside any other points you would like to introduce.

1. How should the current emphasis on stakeholder engagement be incorporated into overall governance processes for innovative technologies?
2. Beyond this emphasis on stakeholder engagement, what other issues should be addressed under the heading of responsibility particularly as part of the governance of innovation processes rather than research?
3. Have you considered issues related specifically to Responsible Research and Innovation (RRI) in the context of synthetic biology and gene editing and if so what are your views on the best way to progress that agenda?
4. What role could an aspirational framework standard play in the process of ensuring responsible behaviour? See, for example ISO 26000, the international guideline on Social Responsibility.
5. Is there any value in an approach that, in the interests of overall balance, also links responsible innovation to the concepts of responsible regulation and responsible engagement?

Annex 4.

DEFINITIONS

Business model describes, for a sector or sub-sector, how firms operating within it can create, capture and deliver value. It acts as a guide to incumbent and future businesses aiming to increase the amount of value they can create or capture, often through the adoption of innovative technology.

Value chain describes the full range of activities required to bring a product from conception to market and end use, including design, production, marketing, distribution and support to the final consumer. It can be covered by a single, probably large, firm or involve multiple firms, nationally or globally. Each firm will be working to a different business model, appropriate to their role in the overall value chain.

Disruptive innovation involves discontinuities in innovation pathways, requires new areas of research and development (R&D), creation of new modes of production and new markets. It can lead to sectoral transformations and the displacement of incumbent companies, and the creation of entirely new sectors with significant societal and economic benefits. In a few cases it may also lead to stakeholder concerns at an early stage of development and there may be no obvious regulatory precedent to govern potential human and environmental safety issues. For a disruptive innovation, there may be no existing business model to be followed, and there may also be a need to create a new value chain, or to create a new role in an existing value chain.

Incremental innovation fits well with the current business model of a firm. It generates competitive advantage and contributes to the economy through more efficient use of resources, or elimination of wasteful or environmentally damaging practices. It is less likely to lead to stakeholder concerns, is more likely to have a pre-existing regulatory framework in place, but will not lead to sectoral transformations.

Governance. The concept of governance, at its simplest describes a process of exercising authority, e.g. the way that a city, company, or organisation is controlled, either by the people who run it or by an external authority. Most definitions rest on three dimensions: authority, decision-making and accountability, determining who has power, who makes decisions, how other players make their voice heard and how account is rendered (<http://iog.ca/wp-content/uploads/2014/11/About-IOG.pdf>). For the PAGIT project it includes formal legally based regulation of new technologies, other 'softer' approaches using standards and guidelines, and the processes by which authority and influence on decisions are exercised through stakeholder engagement as a component of RRI.

Regulation is an important component of the governance process and is defined as the act of rule-making by a government or other authority in order to control the way something is done or the way people behave (<https://www.collinsdictionary.com/dictionary/english/regulation>). In the PAGIT project it refers to regulations with legal authority exercised by a state or international authority.

Consensus Standards are voluntary standards that are developed through the cooperation of all parties who have an interest in participating in the development and/or use of the standards. Consensus requires that all views and objections be considered, and that an effort be made toward their resolution. Consensus implies more than the concept of a simple majority but not necessarily unanimity (<http://www.ses-standards.org/?58>).