PROPORTIONATE AND ADAPTIVE GOVERNANCE OF INNOVATIVE TECHNOLOGIES (PAGIT):

A FRAMEWORK TO GUIDE POLICY AND REGULATORY DECISION MAKING

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Table of Contents

Acronyms

AIMD	Active implantable medical device
BEIS	Department for Business, Energy and Industrial Strategy
BSI	British Standards Institution
CE	Conformité Européene (accreditation mark on a Medical Device)
CRI Standard	Corporate Responsible Innovation Standard
CRIF	Consolidated Responsible Innovation Framework
CRISPR	Clustered regularly-interspaced short palindromic repeats
CSR	Corporate Social Responsibility
DEFRA	Department of Environment, Food and Rural Affairs
EC	European Commission
EFSA	European Food Safety Authority
ERF	European Risk Forum
EU MD Regulation	EU Medical Devices Regulation
FinTech	Financial Technology
GE	Gene editing
GM	Genetically modified
GMO	Genetically modified organism
HSE	Health & Safety Executive
ISO	International Standards Organisation
OECD	Organisation for Economic Cooperation and Development
PAGIT	Proportionate and adaptive governance of innovative technologies
PAS	Publicly available specification
R&D	Research and development
REACH	EU Registration, Evaluation, Authorisation and restriction of Chemicals Regulation
REng	Responsible stakeholder engagement
RI	Responsible innovation
RR	Responsible research
RRI	Responsible research and innovation
SB	Synthetic biology
SME	Small and medium-sized enterprise
TALEN	Transcription activator-like effector-based molecule
TRL	Technology Readiness Level
US FDA	US Food and Drug Administration
ZFN	Zinc finger nuclease

1. Introduction

1.1 Background

Innovation is expected to form the future basis of national prosperity in the UK[1] and internationally[2]. The UK Industrial Strategy Green Paper has proposed 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 regulatory systems more proportionate and adaptive to the needs of innovative technologies. The regulatory system adopted for a new technology will determine:

- the innovation strategies of companies;
- the extent to which the disruptive innovations that could respond to currently-unmet societal needs are able to be developed;
- the innovativeness of industry sectors;
- their geographic location and scale of operations; and ultimately
- the relative competitive advantage of the regions and nations of the world.

Important questions about how new developments will be regulated and brought to market and how stakeholders will be engaged at various points in their development, have traditionally been decided on the basis of serendipitous interactions, pressures and counter-pressures from actors with a variety of motivations. The framework developed for this project will support improved, more evidence-based policy and regulatory decision making that takes account of the needs of innovative technologies and at the same time continues to ensure safety, quality and efficacy of the final products.

The report's conclusions are relevant to a broad range of innovative technologies and sectors where the UK sees itself as leading in the field. These include autonomous and low-emission vehicles, FinTech, robotics, aerospace, battery technologies, chemicals and industrial biotechnology and life sciences (pharmaceuticals, cell therapies, gene editing, synthetic biology, stratified medicine, agricultural and food technologies).

The framework includes a role for standards that integrates them more constructively and consistently into governance and regulatory systems than has been the case in the past. It incorporates three principles to guide decision making - the **innovation principle**, originated by the European Risk Forum (ERF)[3] and adopted widely throughout the EU[4], and the regulatory **principles of proportionality** and **adaptation**[5].The contribution of standards to implementing these principles lies partly in their diversity and ability to cope with a broad

[1] HM Government (2017) *Building Our Industrial Strategy: Green Paper*, Jan. 2017. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/586626/building-our-industrial-strategy-green-paper.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] European Risk Forum (ERF) (2015) *The Innovation Principle – Overview.* (http://www.riskforum.eu/uploads/2/5/7/1/25710097/innovation_principle_one_pager_5_march_2015.pdf)

[4] 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)

[5] 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

range of circumstances (e.g. covering products, processes, manufacturing and organisational behaviour), partly in their flexibility in the face of a rapidly evolving technology landscape, and partly in their capacity to achieve consensus across the perspectives of a broad range of stakeholders.

Better governance decisions about innovative technologies are expected to come from the targeted consideration of the synergistic or competing requirements of innovators, regulators, policy makers and stakeholders. Guidelines and standards developed to support this process will contribute to the UK government's desire to lead internationally in developing a regulatory test-bed for innovative technologies[6].

A fundamental shift in conventional regulatory thinking proposed here is that the key to delivering the above three principles lies in considering first the extent to which an innovative technology will be disruptive or incremental in its impact on company business models and sectoral value chains before going on to determine the criteria that will be adopted for regulatory approval.

A novel and increasingly important aspect of the governance of innovation systems is the extent to which key actors behave responsibly. The proposed standards-based approach will foster responsibility in all key actors with interests and concerns relevant to an innovative development, including industry, stakeholder organisations and citizens more generally, building on understanding the distinctions between disruptive and incremental innovation.

1.2 Report Structure

Section 2 describes the project objectives and deliverables.

Section 3 outlines the revised PAGIT 2 Framework, building on the three principles (innovation, proportionality and adaptation), incorporating the concepts of disruptive and incremental innovation and building on discussions in interviews and workshops.

Sections 4 – 6 summarise the outcomes of three case studies with a focus on strategic questions about criteria for regulatory choices, to inform future policy and regulatory decisions specific to these technologies. These sections also contribute to further development of the framework and associated guidelines. Free-standing case study reports will provide more detailed analyses based on the discussions with interviewees and workshop attendees.

Section 7 outlines the overall conclusions from the project, including guidelines for applying the framework to deliver adaptive and proportionate regulation and responsible innovation, and improved overall governance through a standards-based approach to responsibility in both innovation and engagement. It also proposes next steps and further developments.

Annex 1 lists definitions of technical terms used in this report.

Annex 2 summarises the types of standards developed by the British Standards Institution (BSI).

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[6] BIS Open Consultation (2016) *National Innovation Plan: call for ideas.* Policy Paper PP06/16 http://www.ipfederation.com/document_download.php?id=3329

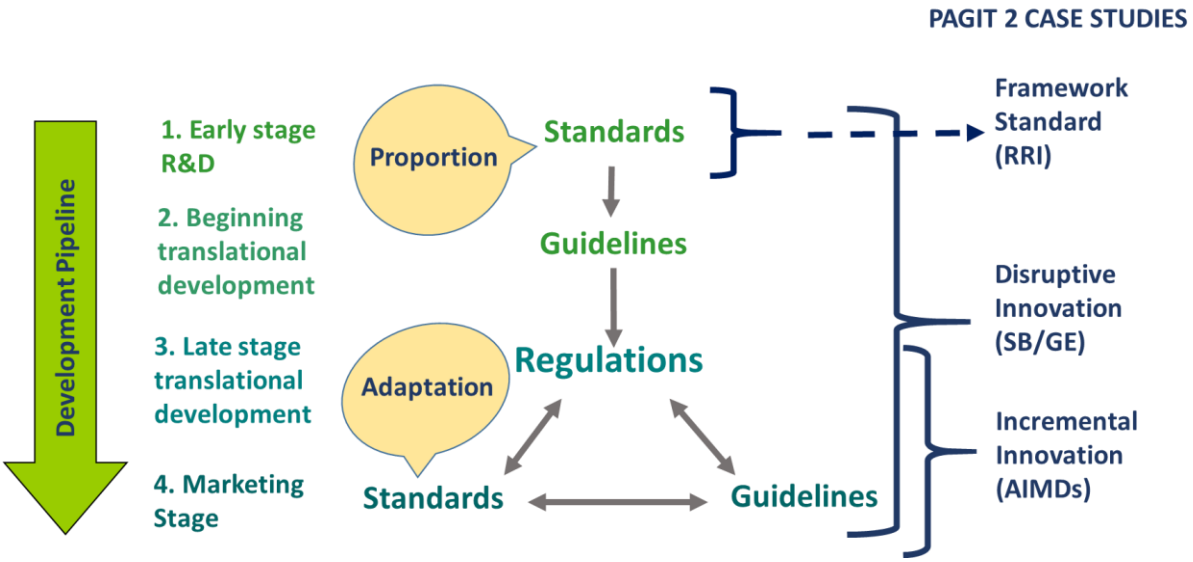
2. PAGIT 2 project aims and outcomes

2.1 Project objectives

The PAGIT 1 project[7] was a broad-brush exploration of the potential roles of standards in contributing to proportionate and adaptive governance of innovative technologies, as illustrated in Figure 1. PAGIT 2 demonstrates how this approach would work, how policymakers or regulators could use it in practice, and how the outputs can be framed so that policymakers and regulators will support the process.

Both PAGIT projects also support BSI's intention to develop specialised and authoritative knowledge to enable it to become a globally recognised and trusted voice in the wider innovation conversation.

Figure 1. Framework from Phase 1 PAGIT Project



PAGIT 2 objectives are:

1. To develop an expanded, mature version of the Phase 1 PAGIT framework considering:
   (i) An integrated role for standards in interaction with formal regulations in the governance of emerging innovative technologies;
   (ii) Where there are generic elements that can apply to all innovative technology sectors and where sector-specific elements will be required;
   (iii) How to deliver greater proportionality and adaptation in regulatory systems through the development or modification of standards at pre-regulatory and/or post-regulatory stages of the innovation pathway.
2. To apply the revised framework to two advanced innovative technology sectors, **synthetic biology/gene editing (SB/GE)** and **active implantable medical devices (AIMDs)**, illustrating the different needs of disruptive and incremental innovations.

[7] Tait, J. and Banda, G. (2016) *Proportionate and Adaptive Governance of Innovative Technologies: the role of regulations, guidelines and standards*, British Standards Institution and BEIS, (http://www.bsigroup.com/research-pagit-uk)

3. To scope an aspirational consensus standard on **Responsible Research and Innovation (RRI)**, including both Responsible Innovation (RI), and Responsible Stakeholder (REng) Engagement.
4. To open a dialogue with research, industry and policy/regulatory partners and other interested stakeholders relevant to each case study.
5. Given stakeholder consensus, to develop a plan for implementation of the proposed standards approach for each case study.

The project was funded by BEIS/BSI, supplemented by a grant from Edinburgh University's ESRC Impact Grant. The adoption of the case study on synthetic biology/gene editing was approved by the Synthetic Biology Leadership Council at its meeting on 14th July, 2016, and subsequently by BSI; and the choice of case study on AIMDs was approved by BSI on 18th October 2016.

2.2 Research approach

Telephone interviews were conducted for each case study with researchers, companies, policy makers, regulators and other stakeholders, and workshops were held in London for the SB/GE and RRI case studies. Most participants had senior advisory or decision making roles in their organisations and approximately 30% of workshop attendees were also involved in the project as interviewees. Interviews and workshop proceedings were recorded and transcribed.

2.3 The Brexit context

The outcome of the Brexit referendum created the opportunity to advise the UK Government on reconsideration of our regulatory systems as responsibility is transferred from the current EU authorities to UK bodies.

For AIMDs, the most logical regulatory choice for the UK would be to ensure access to future EU markets by closely mirroring the requirements of EU regulatory systems. However, within this constraint there will be opportunities to adapt the standards and guidelines that support implementation of regulatory systems, potentially leading to significant savings for the companies affected and enabling innovative developments that would otherwise have been abandoned to reach a viable market.

In contrast, the EU regulatory system for genetically modified (GM) organisms (and potentially for the products of SB/GE) has been heavily criticised. It has severely limited the European market for such technologies and has disadvantaged European companies in international markets[8,9]. The Brexit context creates an opportunity to adapt the UK's future regulatory approach for advanced biotechnologies like synthetic biology and gene editing, with their key roles in underpinning and shaping the bioeconomy, to enable the UK to participate more proactively in international governance systems and to be a more significant player in the global bioeconomy.

[8] 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)

[9] Tait, J. (2009) Governing Synthetic Biology: Processes and Outcomes. In eds. M. Schmidt *et al.*, *Synthetic Biology: the Technoscience and its Consequences*. Dordrecht NL: Springer, pp 141-154.

2.4 Project outcomes

The project outcomes include:

(i) A revised, expanded framework that policy makers and regulators can use to determine the optimum governance system for new advanced innovative technologies.
(ii) Guidelines for industry and regulators based on the PAGIT Framework, covering
(a) choice of a new regulatory system and
(b) targeted adaptation of an existing regulatory regime;
(iii) Roadmaps for standards-related initiatives based on the case studies; and
(iv) Guidelines for development of an RRI-related framework standard on 'responsibility in the development of advanced innovative technologies'.

3. Development and implementation of the PAGIT 2 Framework

The PAGIT 2 Framework introduces a novel approach to governance of innovative technologies. It includes a more formally-integrated role for standards within regulatory systems, and also within 'softer' governance approaches to deliver proportionality and adaptation across a broad range of innovative technology sectors and to support 'responsibility' in innovation related developments. It is framed around the following concepts:

(i) It requires decision makers to consider the extent to which an innovation is disruptive or incremental;
(ii) It applies the principles of proportionality and adaptation selectively to the development of regulatory systems depending on the degree and location of the expected disruption caused by the technology; and
(iii) It incorporates a framework Responsibility Standard with component standards covering Responsible Innovation and Responsible Engagement, both of which are also related to the extent to which an innovation will be disruptive of incumbent business models and value chains.

How we choose to 'capture' an innovation within a specific regulatory system will define the future shape of the new industry sectors that form around an innovative technology and determine its contribution to national economies. Past choices have reflected a range of pressures from industry, policy makers, regulators and societal lobby groups:

- the choice to treat cell therapies as 'drugs' for regulatory purposes[10];
- regulating biopesticides through the chemical pesticide related regulatory system[11];
- regulation of GM crops as 'a plant pest' (US regulation of GM crops)[12];
- regulating all GM organisms according to the process (GM) by which they were produced (EU Regulatory System)[13];
- regulating GM fish as 'a drug' (US Regulatory system)
- regulation of all agriculture-related products incorporating innovative advanced biotechnology techniques according to the degree to which the product is 'novel' (Canadian regulatory system)[14].

All the above choices have had flaws, some with very significant negative impacts on innovation in the sectors involved. These idiosyncratic approaches to regulatory capture also do not lend themselves to subsequent adoption of evidence-based criteria by which to judge the risks and benefits of a new technology. They will play a major role in deciding what evidence it is deemed appropriate to gather – e.g. the fact that cell therapies are

[10] Mittra, 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#
[11] Chandler, D. *et al.,* (2008) Microbial biopesticides for integrated crop management: an assessment of environmental and regulatory sustainability. *Trends in Food Science and Technology, 19,* 275-283.
[12] US Congressional Research Service (2017) *Advanced Gene Editing: CRISPR-Cas9,* April 28 (2017), p21. R44824; https://fas.org/sgp/crs/misc/R44824.pdf
[13] Conko, G. *et al*. (2016). A risk-based approach to the regulation of genetically engineered organisms. *Nature Biotechnology, 34(5),* 493-503.
[14] Smyth, S.J. (2017) Canadian regulatory perspectives on genome engineered crops. *GM Crops and Food, 8(35),* 35-43.

expected to go through the drugs-based clinical trials system, driving the technology strongly in the direction of being developed exclusively by the pharmaceutical industry sector. As proposed here, basing decisions on regulatory capture on the extent of disruption arising from a new technology allows a more appropriate focus on the expected properties of innovative developments. Given the above inconsistencies, there is ample justification for seeking a better approach to the regulatory capture of innovative technologies, as proposed here.

3.1 Core principles underlying the PAGIT Framework

The **innovation principle** is intended "… to improve the quality and application of EU legislation and as a result, to stimulate confidence, investment and innovation"[15], emphasising its suitability as a starting point for considering the process of regulatory reform. This Framework proposes to implement the innovation principle by embedding the linked **principles of adaptation and proportionality** more formally within regulatory decision making. Although these regulatory principles are widely discussed, there has so far been little constructive thinking on how they could or should be implemented in practice across a broad range of different technologies.

The PAGIT 2 Framework includes the following modifications of the original version.

(i) It expresses the development stages for an innovation in terms of technology readiness levels (TRLs) (Figure 2), increasingly used by policy makers as a planning tool for innovation management[16].
(ii) It distinguishes more clearly the different types and roles of standards and guidelines before and after a decision has been made on the appropriate regulatory system to be applied for an innovative technology (pre-regulatory and post-regulatory) (Figure 3);
(iii) It clarifies where and how to include consideration of:
    a. the extent to which an innovation is disruptive or incremental in its impact on business models and value chains;
    b. the principles of proportionality and adaptation; and
    c. responsibility of key actors in the innovation process.

3.2 A staged approach to the development of regulatory systems for innovative technologies.

The staged decision making process for the PAGIT 2 Framework is designed to enable those involved in the governance system as a whole to learn more about the properties of an innovative technology before making relatively irrevocable decisions on: whether the risks justify the introduction of a legally based regulatory system; if so which of the current regulatory systems would provide the best fit with its properties; and the extent to which the chosen regulatory system would require to be adapted to make it more proportionate to the needs of the technology. This approach runs counter to the more usual exhortation on regulators to decide on the regulatory system for an innovative technology at 'upstream'

[15] European Risk Forum (ERF) (2015) *The Innovation Principle – Overview.* (http://www.riskforum.eu/uploads/2/5/7/1/25710097/innovation_principle_one_pager_5_march_2015.pdf)
[16] 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]

stages of its development (TRLs 1 – 3) before the nature of its benefits and risks are evident or are supported by data, and with potentially dysfunctional outcomes for future viability of an innovative sector[17]. The advantage of the PAGIT approach is that the choice of regulatory precedent will be better informed than previously. Once a decision has been made on a regulatory system it is a difficult, bureaucratic and often sub-optimal process to adapt it later to the emerging properties of an innovative technology.

The decision process associated with the Framework (Figure 3) is as follows.

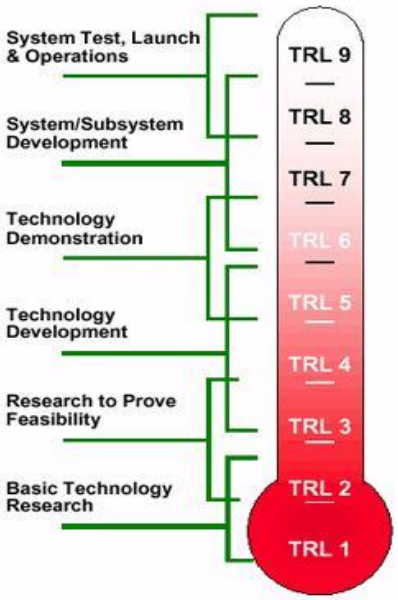
For an innovation classed as disruptive (a relative rare occurrence)

(i) TRL 1-3 (**Pre-Regulatory Standards**). Focus on aspirational or consensus standards to support understanding of the properties of the innovation, including its potential risks and benefits and how they could best be addressed.

(ii) TRL 4-5 (**Pre-Regulatory Guidelines**). From these initial standards, develop more formal guidelines that could then, if necessary, form the basis of a future regulatory system. At this point decision makers should also be open to a conclusion that the proposed guidelines are sufficient to ensure safety, quality and efficacy of the innovation and that legally based regulation is not necessary.

(iii) TRL 6-7 (**Regulations**). Either decide on which existing regulatory system is most appropriate to the properties of the new innovative technology or, for the most radically disruptive technologies, consider devising a new regulatory approach. Legally binding regulations should be couched in general terms relating to their desired outcome and be backed up by post-regulatory standards and guidelines.

Figure 2 Technology Readiness Levels



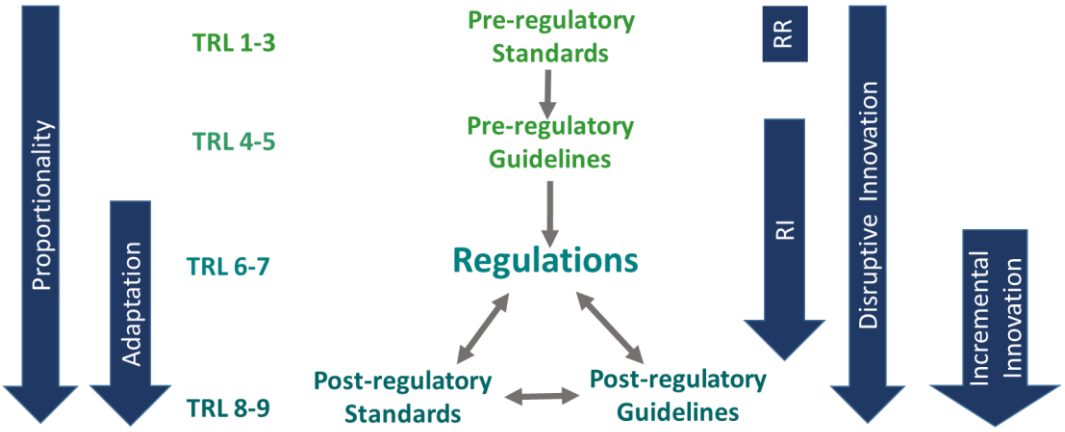
(iv) TRL 8-9 (**Post-Regulatory Standards and Guidelines**). Devise standards (e.g. consensus standards) and guidelines to support compliance with the regulations by those engaged in developing the new technology.

For an innovation classed as incremental (the most frequently encountered type)

As illustrated in Figure 3, for incremental innovation, consideration of appropriate regulatory systems can begin at TRLs 6 – 7, focusing on any necessary adaptation of the prevailing post-regulatory standards and guidelines to ensure that they are proportionate to the properties of the new technology.

[17] 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)

Figure 3 Generic PAGIT Framework



3.3 Operationalising the disruptive – incremental distinction as basis for regulatory decision making

The UK Industrial Strategy Green Paper has recognised the need to support new industry sectors that will be disruptive of established ways of working and to ensure that the innovations on which these sectors will be based are not unnecessarily inhibited. It has also recognised the need to support the more incremental innovations that will improve our international competitiveness in existing industry sectors[18].

Disruptive and incremental innovation are defined for this project as follows[19]:

- **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.
- **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 on which to 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[20].

Linking these concepts to the development of regulatory systems, the more onerous, expensive and lengthy the sectoral regulatory system, the more that sector will be

[18] HM Government (2017) *Building Our Industrial Strategy: Green Paper*, Jan. 2017, p97 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/586626/building-our-industrial-strategy-green-paper.pdf

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

[20] See Annex 1 for definitions of 'business model' and 'value chain'.

dominated by the incremental innovation that fits the business models of very large companies and the more difficult it will be for a competing disruptive innovation to succeed in displacing incumbent company business models. Thus, the regulatory processes we put in place for an innovative technology will determine not just which products and processes are developed but also what scale of company can participate in their development and ultimately the competitive advantage of nations and regions. A departure from conventional thinking on regulation of innovative technologies is our proposal that the extent to which an innovation is disruptive or incremental, should play an important role in early consideration of its future regulation and governance[21] as part of the overall process of enabling more disruptive innovation to be developed and to reach a stage where it can benefit the UK economy.

As stated above, for a truly disruptive innovation there will be no pre-existing business model for innovators to follow – they will need to invent a viable business model in addition to developing the innovation itself. Congruity between the properties of the technology and the eventual business model will be the main determinant of commercial success and this outcome will be strongly influenced by the choice of regulatory system for the new technology. The spectrum of possible relationships between the new business model and those of incumbent industry sectors will include peaceful co-existence, synergy and/or direct competition.

Based on the PAGIT 2 Framework (Figure 3), for a disruptive innovation, governance and regulatory decision making should focus from TRLs 1-5 on the development of pre-regulatory standards and guidelines to inform the eventual decision on the most appropriate regulatory system at TRL 6. The main focus in such a case will be on the Proportionality Principle in the context of the emerging understanding of the benefits and risks presented by the innovation, as it moves across the TRLs, and managing such risks through standards and guidelines (soft law).

For an incremental innovation there is usually an existing regulatory system that can be treated as a precedent, and innovators will benefit from compliance with that regulatory system, beginning at TRL 6. Here the Proportionality and Adaptation Principles will both be relevant to enable targeted adaptation of the existing regulatory system to ensure that it is proportionate to the benefits and risks of the innovative development.

Adaptive decisions for incremental innovation at this stage can have significant impacts on the innovation capacity of a sector. For example the US Food and Drug Administration (FDA) decision, to change the guidelines for the conduct of clinical trials for new antimicrobial drugs, brought down the cost of their development by ~50%[22]. Adaptation of post-regulatory standards and guidelines may also be needed, in the direction of strengthening them or adding new ones, to avoid negative outcomes.

Deciding whether an innovation is disruptive or incremental is not always straightforward and the concepts are in practice more fluid than implied in our definitions. For example, our

[21] See Annex 1 for definitions of 'regulation' and 'governance'.

[22] Tait, J., Bruce, A., Mittra, J., Purves J. and Scannell, J. (2014) *Independent Review on Anti-Microbial Resistance: regulation/innovation interactions and the development of antimicrobial drugs and diagnostics for human and animal diseases: Main Report*. 14th Dec., 2014. Report to ESRC for the O'Neill Commission on Antimicrobial Resistance, pp 19-20. http://www.innogen.ac.uk/reports/946.

classification of SB and GE as 'disruptive innovations' and AIMDs as 'incremental', although conforming with descriptions in the relevant literature[23] [24] [25], did not always stand up to the closer scrutiny required for implementation of the PAGIT Framework (see Sections 4 and 5).

Operationalising the 'disruptive-incremental' distinction will require recognition that an innovative technology can be highly disruptive for one industry sector, but relatively incremental for another.

Sectoral impacts will also depend on the nature of the affected value chain and the location of the expected disruption. In some sectors (e.g. pharmaceuticals, agrochemicals) large multinational companies control the entire value chain, including the small companies that they collaborate with, and so will be affected by disruption anywhere across that value chain. In other sectors (e.g. industrial biotechnology) disruption can affect the business models of one of the participating sectors (petrochemicals-based manufacturers of chemical intermediaries) with relatively little impact on companies in the rest of the value chain.

The following examples illustrate these points.

(i) A broad range of sectors of the economy were involved in the development of GM crops in the 1980s, including agrochemicals, seeds, food producers and processors and even petrochemicals. GM crops would have been disruptive of all these business models/value chains to some extent but the disruptive impact was greatest for the agrochemicals sector, impacting on R&D, product manufacture, distribution and markets[26]. GM related innovations would have been much less disruptive for the plant breeders and seed companies where, apart from the R&D stage there would have been little disruption of product manufacture, distribution and markets.

(ii) The sectors that are most challenged by a disruptive innovation will have a strong interest in gaining control of it and the key to gaining such control is often through the regulatory system. For GM crops the choice discussed in the 1980s and early 1990s was whether this technology should be regulated as a new plant variety or as a product of the agrochemical industry (the latter being the chosen option)[27]. This regulatory choice was a key factor in pushing development of GM crop technologies into the control of the agrochemical industry. Regulation through the plant variety system would probably have led to the seeds sector taking the lead in bringing this technology to market and the shape of the agro-biotechnology sector may have been very different from today's version. There may also have been a very different European public reaction to the technology.

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[23] Datta, P. (2016) *Is synthetic biology a game-changing technology? Disruptive potential exceeds 3D printing and autonomous vehicles.* GEN Exclusives, July, 2016. http://www.genengnews.com/gen-exclusives/is-synthetic-biology-a-game-changing-technology/77900693

[24] TMF(2016) *Fourteen technologies that will shape cancer care.* http://medicalfuturist.com/technologies-that-will-shape-the-future-of-cancer-care/

[25] Stirling, C., Shehata, A. (2016) *Collaboration – the future of innovation in the medical device industry*. A KPMG Report: https://assets.kpmg.com/content/dam/kpmg/pdf/2016/05/the-future-of-innovation-for-the-medical.pdf

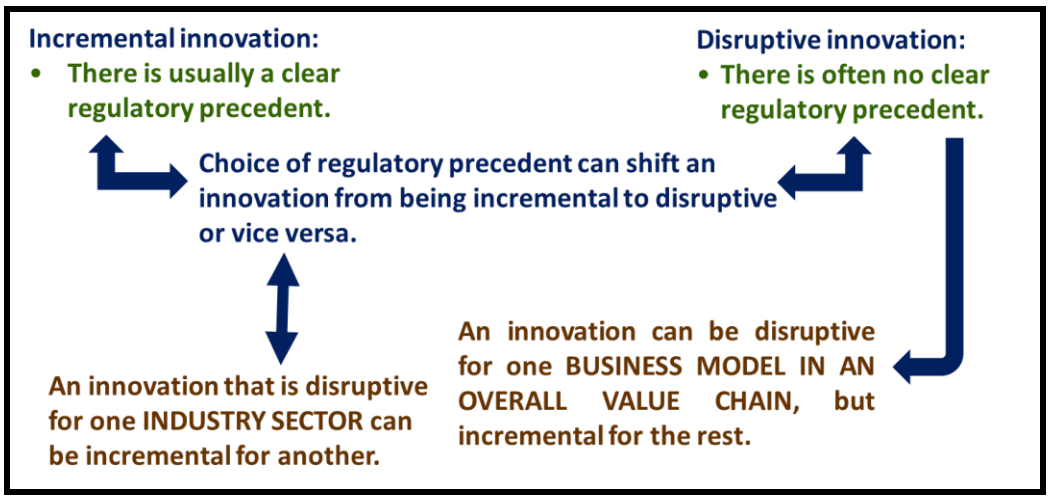
[26] Tait, J. and Chataway, J. (2007) The governance of corporations, technological change and risk: examining industrial perspectives on the development of genetically modified crops. *Environment and Planning C: Government and Policy, 25*, 21-37.

[27] Tait, J. and Levidow, L. (1992) Proactive and Reactive Approaches to Risk Regulation: the Case of Biotechnology, *Futures*, April, 1992, pp 219-231

(iii) An innovation would be presumed to be incremental where it bears a resemblance to the products of an existing sector and the choice of regulatory system to be applied appears unequivocal and is not contested. For example, innovations in AIMD development (Section 4) were classed as incremental in that they are being developed by the existing medical devices sector and appear to fit within an existing regulatory system. However, the recent implementation of the EU MD Regulation, is expected to have a disproportionate negative impact on AIMDs with societally important implications for the future availability of such devices. Where such regulatory change is recent (as in the EU Medical Device Regulation) it should theoretically be possible to open up the innovation environment for AIMDs by adaptation of the post-regulatory standards and guidelines while they are still under development.

These relationships are summarised in Figure 4. The extent to which an innovation is disruptive or incremental is proposed as a basis for deciding on what regulatory basis and at what TRL to enter the PAGIT Framework. Adoption of the disruptive/incremental criterion is particularly justified in the context of the innovation principle in that it focuses attention on innovation processes and regulation/innovation interactions and it can highlight opportunities for regulatory adaptation.

Figure 4. Linking the concept of disruptive innovation and regulatory processes



3.4 Linking RRI to the innovation principle and governance issues

The concept of governance (how authority is exercised over an organisation), as used in this report, includes formal legally based regulation and also softer regulatory approaches based on standards and guidelines and less formal but nevertheless powerful stakeholder influences. RRI, with its strong emphasis on stakeholder engagement is being promoted as an essential component of future EU governance of innovative technologies[28]. It is defined as "… an approach that anticipates and assesses potential implications and societal

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

expectations with regard to research and innovation, with the aim to foster the design of inclusive and sustainable research and innovation"[29]. To date very large sums have been invested in research projects relevant to RRI, but implementation of RI has been patchy[30].

There is now a stronger focus, in words if not yet in deeds, on industry taking a leadership role in scoping the concept of RI, involving a different set of actors with an understanding of how innovations are developed, how they are managed and how policy affects them[31]. RI has links to the Innovation Principle and the concept of disruptive innovation in that stakeholders are most likely to want to engage in dialogue about RI where the innovation concerned is seen to be disruptive. Additionally, engagement about a potentially disruptive innovation can exacerbate conflict rather than diminishing it. When this happens, stakeholders may lobby politically for the adoption of regulatory systems that are disproportionate to the expected risks of the technology[32]. These influences on regulatory decision making demonstrate why it is important to consider RI alongside the regulatory principles of proportionality and adaptation.

The incorporation of a Responsibility Standard within the PAGIT Framework is thus timely and in keeping with the project's aims. It will address the need to develop an approach that companies can use to demonstrate responsible behaviour that is simple to implement and compatible with the challenges of delivering innovation. It will also meet the expectations of a broader range of stakeholders and improve trust in the overall innovation process.

The Framework described in Figure 3 makes it clear that, for incremental innovations, responsible research (RR) is unlikely to be a focus of public attention and should not be routinely undertaken. Where innovation is potentially disruptive, at TRLs 1-3, it is appropriate to consider broadly the nature of the research and the potential novel innovations that may emerge from it (RR) in an open ended dialogue that will be mutually informative for all parties involved, but will not aim to reach a consensus or to make binding decisions on future development or governance of the technology[33,34].

The nature of the discussion and dialogue with stakeholders will change from TRL 4 onwards, once it has become clearer what the innovation will be like and what its benefits and risks might be, and should focus on RI rather than the research and discovery process.

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[29] EC: https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation (accessed 26/06/2017)

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

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

[32] 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)

[33] Tait, J. (2017, in press) From Responsible Research (RR) to Responsible Innovation (RI): challenges in implementation. *Engineering Biology.*

[34] 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)

4. Case study on active implantable medical devices (AIMDs)

4.1 Case study development

The medical device sector has become increasingly important for the healthcare of EU citizens. It employs 575,000 people with total sales amounting to EUR 100 billion. The sector represents some 25,000 companies, of which 95% are Small and Medium-sized Enterprises (SMEs)[35]. The primary focus of this case study was to explore how the newly approved EU Medical Device (EU MD) Regulation (EU) 2017/745 of the European Parliament and of the Council, might affect innovation in AIMDs, and whether and how the process of developing post-regulatory standards and guidelines (TRLs 6 – 9, Figure 3) might be adapted to ensure that they are proportionate to the needs of the most innovative AIMDs.

The following definitions relate to the regulation of AIMDs[36]:

- 'Active Device' means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose or by gravity and which acts by changing the density of or converting this energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be considered to be active devices. Software shall be considered an active device.
- 'Implantable device' means any device, including those that are partially or wholly absorbed, which is intended to be totally introduced into the human body or to replace an epithelial surface or the surface of the eye, by clinical intervention and which is intended to remain in place after the procedure. Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be considered an implantable device.

The majority of interviewees observed that the Regulation had not yet been finalised and that regulators, standards bodies and companies were in the process of assessing the details of the future regulations, standards and guidelines and/or potential implications for their business. The fact that the Regulation was about to be published at the time of conducting the survey and post-regulatory standards and guidelines were still to be developed affected participation in this case study. We interviewed thirteen participants but we were not able to recruit enough participants for the proposed workshop to justify holding it.

The Brexit decision created additional uncertainty and political sensitivity regarding the future transition of the UK regulatory system to the requirements of the EU MD Regulation. AIMDs are an area of innovation where the UK economy is likely to benefit from retaining the prevailing EU regulatory system in order to foster continued trade with EU nations. The AIMD case study proposed to explore whether there would be opportunities, within a future UK regulatory system that broadly follows requirements of the EU Regulation, for standards to contribute to a more proportionate and adaptive regulatory approach that will facilitate innovation.

[35] http://ec.europa.eu/growth/sectors/medical-devices/

[36] Annex 1**:** Consolidated negotiated text - Proposal for a Regulation of the European Parliament and of the Council on Medical Devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009.

4.2 Incremental innovation and regulatory precedents for AIMDs

The medical device industry is highly diverse, with products and technologies ranging from simple tongue suppressors to pacemakers and advanced diagnostic devices[37]. In applying the PAGIT framework to AIMDs, we proposed to show how regulation can be made more proportionate to the needs of incrementally innovative technologies by adaptation of the standards and guidelines in place at TRLs 8 – 9 (Figure 3) for incremental technologies.

The EU MD Regulation was developed in response to the increasing technological sophistication of devices and to safety scandals involving sub-standard materials used for breast implants and hip replacements. The European Commission (EC) submitted proposals to update this framework in 2012 and the Regulation was approved by the EU Parliament on 15 June 2016[38] and adopted without amendments by the EU Parliament on 5 April 2017[39]. The new MD Regulation increases safety compliance through: stricter pre-market and post-market monitoring and certification procedures; strengthened rules for high-risk devices; increased transparency through product data reporting and collection; and improved consumer awareness and protection through product traceability measures. In addition to improving product safety, this will increase the regulatory burden on companies, particularly those developing and producing AIMDs, while offering some potential for adaptation during the three-year transition phase to the new Regulation.[40]

Most new devices, even the more advanced AIMDs, will incorporate incremental innovations for which there will be a clear regulatory precedent. Where the properties of an innovative AIMD have not been anticipated by the EU MD Regulation and the associated standards and guidelines, the fact that these procedures are newly in place and their implementation is in its early stages may make it more difficult to achieve any necessary adaptation to standards and guidelines (TRLs 8 – 9, Figure 3). Some innovative developments in AIMDs may thus be particularly vulnerable in face of these recent developments.

4.3 Implications of the new EU MD Regulation on AIMDs

Interviews with stakeholders explored the potential benefits of the new Regulation on patient safety and efficacy, the challenges the new Regulation posed for companies and their potential effects on innovation. Most interviewees felt that it was too soon to give clear answers to such questions given that companies and notified bodies are still in the process of assessing the new requirements, with the final versions of the relevant standards and guidelines still subject to revisions at the time of the interviews. That said, the consensus among interviewees was that:

- The enhanced requirements in the new EU MD Regulation will indeed improve safety and efficacy;

[37] European Commission https://ec.europa.eu/growth/sectors/medical-devices_en (accessed 1/4/2017)
[38] European Parliament (2016) *Press release. Medical Devices: Health Committee MEPs approve stricter EU safety requirements*, 15/6/2016 http://www.europarl.europa.eu/pdfs/news/expert/infopress/20160613IPR32057/20160613IPR32057_en.pdf
[39] RAPS (2017). *EU Adopts New Medical Device, IVD Regulations,* 5/4/2017 http://raps.org/Regulatory-Focus/News/2017/04/05/27279/EU-Parliament-Adopts-New-Medical-Device-IVD-Regulations/
[40] BSI (undated) White Paper: Planning for implementation of the European Union Medical Devices Regulations – Are you prepared? https://www.bsigroup.com/en-GB/medical-devices/resources/whitepapers/

- The number of notified bodies is already decreasing due to a lack of institutional capacity to oversee the new requirements;
- Increased reporting requirements will increase the costs for companies in bringing new products to market;
- Reporting and clinical data requirements will be particularly high for AIMDs which will also be subject to additional regulatory oversight and review;
- Initially, large established companies will be better positioned to meet the costs of the new requirements.

New requirements for data collection to improve product safety and efficacy are expected to be costly for developers and manufacturers of medical devices. These will include more detailed data regarding the clinical evaluation, clinical investigation and technical specifications and post-market performance than previously required, including registering of adverse effects or damage caused by devices. Based on these data, manufacturers will now be required to submit a full technical file on the device for CE (Conformité Européene) certification, rather than the abbreviated report which was previously required. Perhaps more challenging, particularly for high-risk devices such as AIMDs, is that clinical equivalence for all new devices will now need to be demonstrated through clinical data – foregoing clinical trials will no longer be an option. For some AIMDs, the new Regulation will also require an additional layer of review by a panel of experts to obtain CE certification. Finally, where devices contain identified hazardous materials, stricter requirements will apply. These measures will indeed improve patient safety and efficacy, but they will also increase costs and time to market and may prove difficult to meet for some innovators, particularly for high risk devices such as AIMDs[41].

4.4 Potential implications of the EU MD Regulations on innovation in AIMDs

SMEs in the bio-medical area are more likely than large established firms to develop innovations that are disruptive or that, while considered incremental, will require major adaptation to post-regulatory standards and guidelines if they are to be adopted. For this reason the UK government is providing increased funding and other incentives to support small firm growth and to facilitate the commercialisation of basic and applied research[42]. Interviewees confirmed that the majority of AIMDs on the market are produced by large, predominantly multinational companies, with very few if any small companies emerging into the AIMD area. The increased costs associated with the EU MD Regulation will reinforce this imbalance and may even deter some of the large companies currently producing AIMDs from pursuing further innovation. This raises concerns that, under the new Regulation, the number of new and improved AIMDs will be more limited than before.

Innovative AIMDs were seen to have the potential to radically change and improve diagnostics, treatment and monitoring of disease outcomes, as well as leading to new approaches to drug delivery. Some of these developments could open up opportunities to develop new business models and value chains and to be disruptive of incumbent industry sectors, but this is unlikely to happen without willingness by all the parties concerned to

[41] BSI (undated) White Paper: How to prepare for and implement the upcoming MDR – Dos and don'ts. https://www.bsigroup.com/en-GB/medical-devices/resources/whitepapers/

[42] HM Government (2017) *Building Our Industrial Strategy: Green Paper*, Jan. 2017, p97 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/586626/building-our-industrial-strategy-green-paper.pdf.

engage in discussions on potential post-regulatory adaptation of standards and guidelines. It is possible that some future developments based on advanced innovative technologies, involving software and communication technologies will be sufficiently disruptive to require reconsideration of the MD Regulation itself through the development of pre-regulatory standards and guidelines.

The regulatory process is now at the stage of developing post-regulatory standards and guidelines to support companies in meeting the requirements of the regulator at TRLs 7 – 9. It is highly likely that there will be a need for some adaptation of these arrangements to ensure that they are proportionate to the benefits and risks of the most innovative devices in Categories 2b and 3. With clinical data reporting for medical devices set to increase, adaptation for clinical trial requirements is an area where there may be opportunities to devise a smarter approach to support compliance with the Regulation. Given the current stage of development of the EU MD Regulation and the supporting standards and guidelines, there is an opportunity to consider such adaptations during their development to save time and later costs for both regulators and innovators.

Alternatively, in three years' time once the post-regulatory standards and guidelines have been developed there will be a need to reconsider how these standards and guidelines could be adapted to be more proportionate to the needs of the more complex innovative AIMDs currently in early development (TRLs 1 – 3).

4.6 Conclusions and recommendations

It is too soon to gauge the implications of the EU MD Regulation for innovation in AIMDs. The new requirements will improve patient safety and efficacy, but costs to manufacturers of AIMDs will increase, reinforcing the dominance of large companies in this area and raising the barriers for new innovative firms looking to enter the AIMD market. This is particularly pertinent given that interviews indicated that new AIMDs, unlike most new medical devices which are based on incremental innovations, are potentially disruptive of existing value chains and business models and may require more adaptation of the supporting framework surrounding the EU MD Regulation than currently envisaged. The most difficult regulatory challenges are likely to be in the grey area between highly novel devices and those with only incremental changes.

BSI has two distinct roles in the governance of MDs:

(i) It is a Statutory Notified Body providing regulatory and quality management reviews and product certifications for medical device manufacturers.
(ii) It also works with companies to develop standards and provide guidance for companies in transitioning to the new Regulation.

BSI is thus well placed to understand where innovative developments of medical devices are being inhibited by the regulatory system and whether there are opportunities for adaptation of post-regulatory standards and guidelines to make the Regulation more proportionate to the needs of AIMDs. It could have a useful role, working with MHRA, to identify opportunities to enable small companies to meet new certification requirements in a cost effective way.

In the Brexit context, for AIMDs the primary consideration will be to retain access to European markets by meeting the requirements of the EU MD Regulation.

5. Case study on synthetic biology (SB) and gene editing (GE)

Synthetic biology and gene editing are enabling platform technologies that are expected to form the basis of the bioeconomy and to transform production processes in many areas of the developed and developing worlds. The value of the UK bioeconomy is estimated to be £150 Bn GVA, increasing by another £40 Bn over the next decade. UK investment in synthetic biology to date is over £300 M, supplemented by substantial private investment, leading to an expected synthetic biology market in the UK of £10 Bn by 2030[43].

SB and GE are being widely described as 'disruptive' innovations[44,45,46,47], and that was the starting point for this case study (Figure 1). However, on further reflection many of the expected applications of these technologies will not be disruptive of the current business models of incumbent agro-biotechnology companies that are based on related GM technologies or of pharmaceutical companies that currently develop biopharmaceutical products. If the impact on business models is mainly incremental the focus should be on post-regulatory standards and guidelines and the extent to which, as currently constituted, they will be able to comply with the principles of innovation, proportionality and adaptation (Section 3.3).

The two areas of application of SB and GE considered here are: (i) modification of crop plants, most relevant to the agro-biotechnology industry sector, and (ii) modification of micro-organisms with applications mainly in industrial biotechnology. Crop related developments, and to a much lesser extent industrial biotechnology, continue to be the subject of intense and often heated debate on whether and/or how they should be regulated. In the EU there is agreement among scientists, innovators and *some* regulators, on the need for more proportionate and adaptive regulation of innovation in the crop-related area, but much less pressure for change in regulation of the contained use of GM organisms in industrial biotechnology, currently seen as unproblematic by the industry sector. Given the Brexit decision, there is also considerable pressure in this area of regulation for the UK to break with the EU regulatory system itself and to design a different approach that builds on regulatory experience in non-EU countries. In the case of GM and related technologies (SB and GE) there could be considerable advantages in opening up trading opportunities with the rest of the world, and little to lose, by adopting a different regulatory approach from that of the EU.

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[43] Synthetic Biology Leadership Council (SBLC) (2016) *Biodesign for the Bioeconomy: UK synthetic biology strategic plan, 2016.* https://connect.innovateuk.org/documents/2826135/31405930/BioDesign+for+the+Bioeconomy+2016+-+DIGITAL.pdf/0a4feff9-c359-40a2-bc93-b653c21c1586

[44] McKinsey and Company (2016) *Exploring the disruptive potential of synthetic biology.* (June 2016) http://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/exploring-the-disruptive-potential-of-synthetic-biology

[45] Datta, P. (2016) *Is synthetic biology a game-changing technology? Disruptive potential exceeds 3D printing and autonomous vehicles.* GEN Exclusives, July, 2016. http://www.genengnews.com/gen-exclusives/is-synthetic-biology-a-game-changing-technology/77900693

[46] Law, C. (2015) *Could CRISPR gene technology be a disruptive innovation?* 3 Dec, 2015. https://www.linkedin.com/pulse/why-crispr-cas9-gene-editing-technology-may-disruptive-robert-law

[47] Talbot, D. (2016) *10 Breakthrough Technologies: precise gene editing in plants.* MIT Technology Review, March/April 2016. https://www.technologyreview.com/s/600765/10-breakthrough-technologies-2016-precise-gene-editing-in-plants/

5.1 Crop related developments

5.1.1 The extent of disruption of incumbent business models

When GM crops were developed in the 1980s, they were disruptive across all stages of development (R&D, product manufacture, distribution and marketing) for the agrochemical companies that developed them[48]. However, GM technologies are now well assimilated within agro-biotechnology sector business models and SB and GE related innovation are likely to be seen by these multinational companies as incremental extensions of the innovation pathways linked to large scale GM commodity markets (corn, cotton, soya and canola).

However, SB and GE do have some potential to be disruptive in that they open up opportunities for smaller companies to create new more specialised niche markets in areas that are not currently served by the agro-biotechnology multinationals and are not of interest to them (e.g. Okanagan Specialty Fruits Inc.[49]). This emergent sector could grow significantly and begin to disrupt the business models of traditional plant breeders and eventually even of the incumbent agro-biotechnology sector. Given the challenges of feeding a growing world population with less use of pesticides and other inputs, and coping with the impacts of climate change on growing conditions, this is a likely outcome but it will depend on decisions still to be made in most countries on how the products of GE and SB will be regulated. The countries that make the most proportionate and adaptive regulatory decisions will see the greatest economic, societal and environmental benefits from these new crop based sectors and markets.

5.1.2 Regulation/innovation interactions

Within the PAGIT Framework, where an innovation has been identified as disruptive, consideration at TRLs 1 – 5 of the nature, extent and location of the disruption can guide initial stages of decision making on how to regulate it. **Relevant guidance for policy makers and regulators is that, when deciding on a future regulatory system for a potentially disruptive technology, they should consider the regulatory system in operation for the sector for which the technology will be least disruptive**[50]. This would contribute to meeting the innovation principle, and it would then be followed up by evidence-based criteria to ensure that the regulatory system adopted is proportionate to the risks and benefits of the technology. The benefit of this aspect of the PAGIT approach is that it would avoid inhibiting some potentially active companies from taking part in delivering either disruptive or incremental innovation related to the new technologies. Adoption of this guideline, in the 1980s and early 1990s, could have led to the choice to regulate GM crops using the plant variety regulatory system (Section 3.3), with potential facilitation of the uptake of these innovations in the EU. The choice to regulate GMOs as a product of the agrochemical companies led to significant disruption of the business models of these companies at the time. However, they have now built new business models based on GM technologies and for them SB and GE based innovation would not be disruptive.

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[48] Chataway, J., Tait, J. and Wield, D. (2006) The governance of agro- and pharmaceutical biotechnology innovation: public policy and industrial strategy. *Technology Analysis and Strategic Management, 18(2),* 1-17.
[49] Okanagan Specialty Fruits Inc, Canada [http://www.okspecialtyfruits.com/arctic-apples/]
[50] 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

Where SB and GE can be treated as incremental innovations, within the PAGIT framework they could potentially be regulated through adaptation of the current regulatory system for GM related innovations to make sure that its provisions are proportionate to the properties of new developments. This would be a logical approach if the current EU regulatory system were not widely regarded as a failure of evidence-based risk regulation, mainly because of the political overlay applied by the European Parliament to the science-based evaluations conducted by the European Food Safety Authority (EFSA)[51].

Among the participants in this project, those employed in multinational agro-biotechnology companies saw few problems in meeting the requirements of the current EU regulatory system, apart from the overlay of political factors on decision making, preventing the introduction of GM crops to EU markets. For them, merely removing the EU political influence on decision making would be sufficient to enable innovation without any additional adaptation of the current regulatory system.

However, the scientists and smaller companies working towards more niche markets for future developments of SB and GE would not be able to bear the costs associated with the current system. Enabling development of these more disruptive developments based on SB and GE would require pre-regulatory decisions on standards and guidelines to be made at the current TRLs for these technologies (~4 and 5), potentially leading to adoption of a different regulatory system from that of the EU or to the decision that no further regulation is needed, beyond the pre-regulatory standards and guidelines.

Considering other possible regulatory jurisdictions, the Canadian government has adopted a system based on the criterion of 'novelty', capturing within the regulatory system any 'plants with novel traits' (PNTs). This system has approved for commercial production at least ten plants developed using SB and GE and is described as "… a science-based regulatory system that is flexible and capable of responding to new innovative products and technologies without having to completely cease production approvals as is the case within the EU". The system is also claimed to be consistent with the regulatory system of the USA[52]. Participants in the PAGIT project generally commented favourably on the Canadian system, but noted that it also captures conventionally bred crops that have not previously been regulated.

Although the US regulatory system has enabled GM crops to be developed and grown on a large scale in many countries globally, it has not been without criticism for what are described as 'regulatory oddities', for example treating a genetically modified fish as a 'drug' subject to US FDA oversight, and a GM crop plant as a 'pest' subject to oversight by the US Department of Agriculture Animal Plant Health Inspection Service[53]. This is seen as increasing the costs for companies by requiring them to go through several different

[51] Mittra, J., Mastroeni, M. and Tait, J. (2014) *Engaging with Uncertainty and Risk in Agricultural Biotechnology Regulation: Delivering Safety and Innovation.* Report from ESRC Knowledge Exchange Project with Syngenta, Jan. 2014. http://innogen.ac.uk/reports/883.

[52] Smyth, S.J. (2017) Canadian regulatory perspectives on genome edited crops. *GM Crops and Food*, *8,* 35-43.

[53] Gilliam, C. (2010) *Special Report: Are regulators dropping the ball on biocrops?* Reuters: Politics, April 13, 2010. [http://www.reuters.com/article/us-usa-gmos-regulators-idUSTRE63C2AJ20100413?feedType=RSS&feedName=everything&virtualBrandChannel=11563]

regulatory systems before commercialising a product[54]. Although this clearly has not inhibited commercialisation by multinational companies it could have a negative influence on the innovation-related behaviour of smaller companies. The US regulatory system has proposals but not yet a solution for the future regulation of GE-related crop products[55,56].

Many project participants emphasised that we should treat SB and GE differently for regulatory purposes. Reasons given related to the difference between the process of GE (with the lack of ability to identify any human-induced changes in the final organism) and SB which introduces identifiable novel gene constructs. These reasons for the separate treatment of GE and SB are not particularly convincing but beneath them lies a deeper concern to find a means to remove GE, as a potentially disruptive innovative technology, from the politicised EU regulatory system. This provides an example of the distortions of reasoning and choice that are introduced into a regulatory system when it is based on political expediency rather than evidence of hazard and risk[57]. The case of SB and GE then illustrates how these distortions can be perpetuated over future generations of innovative technologies, affecting future regulatory systems as well as the competitive position of industry sectors, regions and nations. If a means can be found, as proposed here, to regulate GM and all associated innovations by a system that meets the three principles (innovation, adaptation and proportionality) then such artificial separation between the regulation of SB and GE should not be necessary.

5.2 Industrial biotechnology

5.2.1 The extent of disruption of incumbent business models

Today's markets for chemical feedstocks to develop drugs, detergents, plastics, synthetic fabrics, flavours, fragrances, enzymes, food ingredients, etc., are largely served by petro-chemicals based manufacturers. The industrial biotechnology sector could change all this using SB and GE to modify micro-organisms to enable production of a broad range of chemical end products and intermediates. These manufacturers do not usually sell direct to consumers and so, importantly, there is no disruption of the final market or of the business models of the companies delivering products to it.

The production base for this new industrial biotechnology sector has been described in terms of four different business models or value chains[58]:

[54] Tait, J. and Levidow, L. (1992) Proactive and Reactive Approaches to Risk Regulation: the Case of Biotechnology, *Futures*, April, 1992, pp 219-231.
[55] Gallo, M.E., Sargent, J.F. (Jr.), Sarata, A.K. and Cowan, T. (2017) *Advanced Gene Editing: CRISPR-Cas9*. US Congressional Research Service, April 28, 2017, pp21-23. [https://fas.org/sgp/crs/misc/R44824.pdf]
[56] US Government Publishing Office (2017) *Federal Register, 82(12)*, 6367-8. https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01013.pdf
[57] 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)
[58] US National Research Council (2015) *Industrialisation of Biology: a roadmap to accelerate the advanced manufacturing of chemicals.* Washington DC: National Academies Press. http://www.nap.edu/catalog/19001/industrialization-of-biology-a-roadmap-to-accelerate-the-advanced-manufacturing.

(i) *Vertically integrated:* Research and design for bio-manufacturing is performed by corporations that develop the entire process from feedstock sourcing to organism engineering to manufacturing and sales, e.g. pharmaceuticals.

(ii) *Centralised production:* Bio-manufacturing occurs in a small number of very large facilities that take advantage of economies of scale, to produce chemicals with thin margins at large volumes to meet world demand, e.g. petrochemicals or (in the fermentation sector) international scale brewers.

(iii) *Horizontally stratified:* Research and design for bio-manufacturing is performed by different companies, each specialising in a different step along the production process, e.g. small and medium sized bio-based manufacturers of specialty chemical feedstocks (mainly in USA).

(iv) *Distributed production:* Bio-manufacturing occurs in many small scale facilities, using geographically co-located feedstocks and producing product to meet local demand, equivalent to micro-breweries.

In terms of SB and GE related innovation the *vertically integrated* model as adopted by a multinational pharmaceutical company can build on skills already available to the company for production of high value biopharmaceutical products at relatively small scales for global markets. A broader shift to biotechnology-based manufacture is unlikely to be seriously disruptive for such a company.

Considering the differential disruptive impact of SB and GE at different locations in overall value chains. Industrial biotechnology is likely to be most disruptive of the *Centralised Production* business model of the current petrochemicals based manufacturers who have very large investments in major chemical facilities, and where the skills of the staff are unlikely to be transferrable to bio-based manufacture. Alternatively, bio-based manufacture of chemicals would be an incremental shift in the business model for companies with pre-existing skills in large scale fermentation, for example in the brewing sector, although they would need to learn to serve additional, different markets. Other things being equal, it would be reasonable to predict that such companies will be best placed to take on the large scale bio-manufacture of these chemical products. However, because it involves SB and GE, with a legacy of stakeholder activism related to GM crops, this may discourage companies in the food and drinks sector from investing in such developments.

The remaining two business models in the above list, *Horizontally Stratified* and *Distributed Production*, both come into the category of emerging disruptive business models, challenging the incumbent petrochemical companies in this area and potentially competing with large companies with expertise in fermentation-based production. Given the deterrents likely to affect sectors with a Centralised Production model, these SME-based models could be the most likely to succeed in creating an industrial biotechnology sector building on SB and GE. Both involve a new type of SME in the early stages of production: designing and manufacturing the novel micro-organisms needed for fermentation-based manufacturing processes. The SMEs operating these 'design and build' business models have not existed on any scale until the past few years. Their business models are potentially disruptive and they could become an important new emergent sector. However, the extent of growth in this area will depend on the extent to which existing multinational companies with a Centralised Production model develop large scale fermentation based manufacture using engineered micro-organisms, or are replaced by new companies with Horizontally

Stratified or Distributed Production models that are able to succeed and grow in scale and numbers.

5.2.2 Regulation/innovation interactions

So far, the end products of manufacture using industrial biotechnology are the same products that are currently being produced from petrochemicals and they will continue to be regulated in the EU under the Registration, Evaluation, Authorisation and restriction of Chemicals Regulation (REACH). This underscores the need to pay attention to the location and scale of disruption of an innovative technology when considering the need for adaptation of regulatory systems – where there is no disruption of the final markets served by these potentially new business models and value chains there is less likely to be a need for reconsideration of product regulatory systems. However, where the change is to the production process, for the manufacturing companies there may be disruption of existing business models, requiring adaptation of any process related regulatory system.

Manufacture of products developed using GMOs, and probably in future those based on SB and GE, will be regulated through the EU Contained Use Directive and the associated UK Regulations, administered in the UK by the Health & Safety Executive (HSE)[59]. There was general agreement across project participants that this regulatory system operates smoothly and effectively and does not place unnecessary constraints on manufacturers. New developments based on SB and GE could continue to be regulated through the existing EU and UK regulatory systems, engaging with the PAGIT Framework from TRLs 6-9, including adaptation where necessary of post-regulatory standards and guidelines (Figure 3). This approach will contribute, in the Brexit context, to protecting future EU markets for industrial biotechnology companies operating in the UK.

If SB and GE developments were to be taken up primarily by the companies for which they are least disruptive (in the brewing and fermentation sectors), then this could be treated as incremental innovation with a clearly identified, unproblematic regulatory system. However, as noted above a group of highly innovative SMEs is developing new production processes, involving new skills and serving a range of novel as well as existing markets, and these may have the greatest potential to deliver future societal and economic benefits. If this prediction is accurate, it implies the creation of new business models and potentially reconsideration of the adequacy of existing regulatory systems for the manufacturing process. The PAGIT Framework would address these questions through the development of pre-regulatory standards and guidelines, keeping open the option that no further regulation is required, or that the existing UK Contained Use Regulations are adequate for this purpose.

A recurring theme in the discussions for this case study was the need to give balancing consideration to benefits as well as to risks related to the innovation. This could, for example, bring regulations in these areas of industrial manufacture, food and agriculture more into line with the regulatory approaches in health-related areas where the 'responsibility' of such developments is unlikely to be questioned by most stakeholders. However, concerns were also raised that evidence of these benefits may be more contested

[59] EU Contained Use Directive (Directive 2009/41/EC) (http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32009L0041) and the UK Contained Use Regulations (Genetically Modified Organisms (Contained Use) Regulations 2014) (http://www.hse.gov.uk/pubns/books/l29.htm)

than in the health context and could be used to bring political issues more overtly into the implementation of regulatory systems[60]. This would be contrary to the intention in the PAGIT approach to minimise political influences on evidence-based regulation. In discussions, participants generally agreed that benefits could most fruitfully be considered as part of the RI process (Section 7). The approach for RI proposed here would provide a forum whereby stakeholder preferences and perspectives can equitably influence innovation-related choices, and this would be a more effective way to bring questions of expected benefits into decision making on overall governance of innovative technologies.

5.3 Conclusions and recommendations

5.3.1 SB and GE

The Framework supported understanding of the scale and location of disruption of business models for different industry sectors likely to be involved in developing innovation based on these platform technologies. It provided one example, in crop-related developments, where there is an opportunity to redesign a regulatory system including considerations of regulation/innovation interactions, appropriate regulatory precedents and criteria for capture of an innovative development within a regulatory system. The disruption involved for industrial biotechnology lies in the potential emergence of a new innovative sector based largely on SMEs with the capacity to grow and become major players, eventually challenging incumbent petrochemicals based manufacturers.

For crop-related developments of SB and GE, the PAGIT framework should be applied, beginning from the current stages of development at TRLs 1-5 (Figure 3). The development of a different regulatory approach would enable more disruptive innovation to be developed without inhibiting the incremental innovation that will also be beneficial to the economy. It would also guide the UK, and potentially also the EU, towards a regulatory system that meets the principles of innovation, adaptation and proportionality. The state of flux of regulatory systems for GE and SB internationally could contribute to enabling the UK to take a lead, based on this approach, in becoming an international 'regulatory test bed capital' (see Section 1.1).

The proposal put forward by project participants was that GE-based crop developments should undergo initial risk assessment based on a new set of pre-regulatory standards and guidelines to ensure that only the desired changes have been made to the genome and that there are no other changes to the properties of the plant that could present a risk to people or the environment (TRLs 1-5, Figure 3). The novel product could then progress directly to market approval via the plant variety registration system[61], without going through the current GM regulatory system. This is basically the system that was under discussion for GMOs, but not adopted in the 1980s. It is similar to the current US proposals for the GE regulatory system but adds the development of pre-regulatory standards and guidelines (essential to deliver proportionality related to potential risks and benefits). In the context of the Canadian system it would deliver similar outcomes but would not regulate PNTs developed by conventional plant breeding. Given that novelty is not a risk-based criterion,

[60] http://www.synbiowatch.org/2014/10/regulate-synthetic-biology-now-194-countries/?lores; http://www.foe.org.au/throwing-precaution-wind-governments-attempts-thwart-regulation-synthetic-biology; http://www.syntheticisnotnatural.com/; https://libcloud.s3.amazonaws.com/93/eb/6/3136/synbio_vanillin_fact_sheet.pdf

[61] https://www.gov.uk/guidance/national-lists-of-agricultural-and-vegetable-crops

the Canadian system captures within the regulatory system products for which there is no expected risk and so could be seen as violating the principle of proportionality. The capture of conventional plant breeding was seen not to be problematic because of its 'light touch' implementation by the Canadian authorities. However, when drafting a new regulatory system for an innovative technology, it is desirable to ensure that it offers as few opportunities as possible for subsequent politically motivated manipulation.

5.3.2 Industrial biotechnology

The Framework supported understanding of the scale and location of disruption of business models for different industry sectors likely to be involved mainly in developing innovative processes based on these platform technologies. It provided one example, in crop-related developments, where there is an opportunity to redesign a regulatory system including considerations of regulation/innovation interactions, appropriate regulatory precedents and criteria for capture of an innovative development within a regulatory system. The disruption involved for industrial biotechnology lies in the potential emergence of a new innovative sector based largely on SMEs with the capacity to grow and become major players, eventually challenging incumbent petrochemicals based manufacturers.

5.3.3 Key actors

In the UK, crop-based developments involving the release of modified organisms will continue to be dealt with by DEFRA and contained use of modified organisms in industrial biotechnology will be dealt with through the HSE.

The BSI could also play a constructive role in bringing together the various elements of the PAGIT approach, orchestrating dialogue with key stakeholders including companies, and advising and taking part in delivery of pre- and post- regulatory standards. BSI's lack of historic involvement in these areas could be an advantage given the mutual lack of trust among many of the key players.

The Organisation for Economic Cooperation and Development (OECD) is considering the international harmonisation of regulatory oversight for biotechnology-based innovations[62] and this could provide a forum for the proposals developed in this project to have international influence.

5.3.4 The Brexit context

In the Brexit context it will be relatively straightforward for industrial biotechnology to continue to be governed by a regulatory system that builds on the EU Contained Use Directive (2009/41/EC), avoiding any difficulties for UK companies in selling products to future EU markets.

On the other hand for GM crop-related developments there was support from participants for a move by the UK away from the EU regulatory system with a view to allowing some of the more disruptive potential innovations to be developed by SMEs. We looked at both the US and Canadian systems as alternative approaches but neither of these is without problems and this is one area where there is an opportunity for the UK to become a test-bed for future regulation of an important new innovative sector.

[62] http://www.oecd-ilibrary.org/environment/harmonisation-of-regulatory-oversight-in-biotechnology_23114622

6. Case study on a Framework Responsibility Standard

6.1 Linking innovation, regulation and stakeholder perspectives on innovation

[63].

The Responsibility Standard proposed here is designed to address the needs and aspirations of innovators, citizens and stakeholders with the following aims:

(i) To enable equitable consideration of the concerns and aspirations of *all* stakeholders, including innovators themselves;
(ii) To support balanced distribution of responsibility across a range of actors, organisations and sectors;
(iii) To bring into the dialogue a better understanding of innovation and regulatory processes;
(iv) To address issues related to the proportionality and adaptation of regulatory systems;
(v) To support accredited adoption of a Responsibility Standard for all stakeholders in an innovation initiative through the involvement of a respected standards body.

6.2 Delivering responsibility

Across all types of innovation, companies are increasingly expected to demonstrate responsible behaviour. The European Commission[64] described RRI as contributing to the Europe 2020 Strategy on 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". The key areas of RRI are: (i) engagement, (ii) gender equality, (iii) science education, (iv) open access, (v) ethics and (vi) governance. Among the problems inherent in implementing the EU approach to responsibility are: lack of consensus on societal ambitions and values, and on ethical and governance issues; and ambiguities related to open access in commercial environments where intellectual property protection is often a key component of a company's competitive advantage. Also, science education is important but is mainly a government-level rather than an industry responsibility, and gender equality should be seen as general good practice within a company, not linked specifically to innovation.

The PAGIT Framework shifts the RRI perspective more towards industry (RI) and attempts to take account of the needs and perspectives of companies, alongside those of citizens and stakeholders, on a more equitable basis than currently prevails. The following expected outcomes from this process point to an important role for the development of standards:

(i) development of agreed criteria by which companies and external observers can be reassured that innovation is being conducted responsibly;
(ii) a process for structuring dialogue and engagement across all stakeholders to ensure a productive outcome, including reassurance that *all* parties involved in discussions will behave responsibly; and

[63] Tait, J. (2017, in press) From Responsible Research (RR) to Responsible Innovation (RI): challenges in implementation. *Engineering Biology.*
[64] 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

(iii) guidance on the extent to which an innovative development will require reassurance related to the properties of the product or process itself, beyond general responsible behaviour by the company.

The proposed Responsibility Standard will help innovators to meet the requirements of RI and will foster more equitably balanced engagement processes for both innovators and stakeholders. Among project participants there was general support for this approach involving parallel standards for RI and for REng.

6.3 Incremental and disruptive innovation – appropriate targeting of responsibility

he requirement for a responsible approach to research and innovation is most often invoked for developments that are regarded as disruptive. Developments that can be categorised as incremental tend not to give rise to societal demands that they should be scrutinised to ensure responsibility.

For an incremental innovation, there may therefore be no need for additional RI or REng-related initiatives, beyond compliance with a company-level standard dealing with generic issues such as gender equality, open access and ethics. It would be disproportionate to expect a company to undertake detailed scrutiny of each incremental innovation they develop, but legitimate to expect compliance with an overall responsibility standard, for example a Corporate Responsible Innovation (CRI) Standard, building on the International Standards Organisation (ISO) Standard for Corporate Social Responsibility (CSR) (ISO 26000)[65].

For a potentially disruptive development on the other hand, companies are likely to be expected to consider the properties of the innovation itself, its potential risks and benefits and their societal distribution, and contributions to societal needs and aspirations. Understanding the disruptive-incremental distinction may therefore be a useful, but not sufficient, criterion for deciding whether responsibility can be judged on the basis of compliance with a company-level CRI standard or whether more in depth scrutiny will be needed based on the nature of the specific innovation. In some cases, regardless of the degree of disruption likely to be presented by an innovation, societal concerns may be transferred to it from advocacy campaigns or negative experiences with previous generations of similar technologies at a point where they were disruptive (e.g. association of SB and GE with earlier GM technologies), requiring a focus on the nature of the innovative technology itself as well as of the company's compliance with general responsibility criteria.

6.4 Challenges in delivering responsibility

6.4.1 Issues of trust and perception

One motivation for the emphasis on responsibility in innovation processes has been the perceived public distrust of industry and science, with RRI and 'upstream engagement' being seen as the vehicle to restore that trust[66]. However, where RI initiatives have attempted to involve industry they have often encountered a lack of trust by companies in the RI process itself and in the academic actors who have been involved in its development to date. Project

[65] https://www.iso.org/iso-26000-social-responsibility.html

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

participants raised concerns about the biases involved in some engagement processes, resulting in inaccurate perceptions that then became obstacles to an effective RI approach.

A common perception was that engagement initiatives can give a platform to the loudest voices and that these voices do not reflect the concerns or needs of civil society, leading to exaggeration or distortion of the expected risks of a technology. The increasing public distrust of experts was also seen as inhibiting constructive engagement on emerging and potentially disruptive technologies, and all the above factors were seen as contributing to an engagement process that is centred on agenda setting rather than consensus building.

6.4.2 Equitable consideration of risks and benefits

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 potential 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 identifying risks and benefits. Although some participants recognised challenges to this idea, the approach is likely to be more helpful than attempting to include the benefits of innovative technologies within the regulatory system itself.

6.4.3 When and about what to engage.

In the context of SB and GE, project participants suggested that engagement on responsibility should focus on the products being developed using these techniques, rather than on the platform technologies themselves (the process). However, if there is a strong desire on the part of some stakeholders to discuss process-related questions, the engagement process should be open to accommodating this.

On the timing question, there was agreement that engagement about RI should be 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 politicisation of discussions that could take place around hypothetical future properties of a technology where engagement is undertaken at earlier TRLs.

6.5 The proposed PAGIT approach to responsibility

The proposed Framework Responsibility Standard will contribute to the innovation principle by addressing equitably the needs and aspirations of innovators, stakeholders and citizens through two parallel standards-related initiatives, Responsible Innovation (RI) and Responsible Engagement (REng). Involvement of a respected standards body in this process will help to ensure the required balance across perspectives that will enable such an initiative to succeed and to contribute to achieving adaptation and proportionality in future regulatory systems.

There was broad agreement among project participants that a framework standards-based approach would be an effective way to support implementation of RI and REng, in collaboration with industry and a broad range of stakeholders and that the BSI is well placed to lead such a development.

6.5.1 Responsible Innovation Standard

A company attempting to innovate responsibly will need to give attention to two different aspects of behaviour.

(i) The CRI standard will be part of the background to everything the company does as part of its standard operating procedures (e.g. promoting sound practices in employment, business behaviour and ethics). This could be based on the ISO 26000 Corporate Social Responsibility Standard, adapted to include issues relevant to the development of innovative technologies. For incremental innovation, accreditation through such a standard may be all that is necessary to deliver RI without further need for additional engagement with stakeholders, with occasional exceptions.

(ii) For disruptive innovation, and for innovations that may be classed as incremental but which become the subject of public or stakeholder interest (e.g. SB and GE related innovation), a company should consider monitoring specific innovations on a case-by-case basis to cover societal, individual or environmental benefits or risks, as relevant. A Consolidated RI Framework (CRIF) [67] for conducting such evaluations has been proposed, combining the RI Framework developed by the UK Technology Strategy Board[68] with the UK Research Councils' approach based on the activities anticipate, reflect, engage and act (AREA)[69] (see Table 1).

6.5.2 Responsible Engagement Standard

There have been previous proposals that standards should be developed for responsible engagement. For example there is an initiative involving 128 companies developing a standard for responsible corporate engagement in climate policy[70]. Perhaps the most comprehensive initiative is described in an EU report[71] that has proposed the development of standards for REng, with a preference for voluntary standards, but including also a proposal for the development of formal, legally binding EU Directives and Regulations in this area. Both initiatives consider only the responsibilities of innovators and fail to consider those of other stakeholders.

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

[68] 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

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

[70] https://www.cdp.net/en/campaigns/commit-to-action/responsible-corporate-engagement

[71] Expert 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.

Table 1. Consolidated RI Framework

Elements of RI	Issues arising during the project	Organisation Responses			
		Anticipate	Reflect	Engage	Act
Societal Element					
Environmental Element					
Business Practice Element					
Regulatory Element					

Our proposal for a REng standard would require *all* stakeholders to engage responsibly, not just industry, and would take account of experience of past engagement initiatives where stakeholders have used engagement opportunities to frame an innovative technology inaccurately in the public mind, either positively or negatively. The following guidelines are proposed as a starting point for development of such a standard[72].

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. Engagement should be carefully timed: too early (upstream) and its value will be undermined by uncertainty about the nature of future developments; too late and stakeholder opinions and political positions may have become entrenched so that accommodation will be more difficult to achieve.
3. Accept that consensus may not be attainable and manage expectations accordingly.
4. Extend the dialogue to include the nature of innovation processes for translation of scientific discoveries to products in a market place, and the relevant regulatory systems, and the constraints they will impose on innovation outcomes.
5. Ensure a balanced consideration of benefits and risks associated with innovative technologies.
6. Do not allow the values and interests of one stakeholder group to restrict the freedom of choice of others.
7. Include standards for the quality and breadth of evidence that is proposed as a basis for decision making.
8. Where there are conflicting values and interests, be equitably sceptical about the impartiality of evidence presented in support of a case.

[72] Lyall, C. and Tait, J. (2017, in press) Beyond the Limits to Governance: new rules of engagement for the tentative governance of the life sciences. *Research Policy.*

9. Where there is conflicting evidence, consider carefully the expertise of those promoting the evidence, including both scientific and experiential expertise, and weight it accordingly.

These criteria extend some way beyond those normally proposed for engagement in the context of RRI and they would contribute directly to meeting the innovation, adaptation and proportionality principles in the delivery of RI.

7. Conclusions and recommendations

7.1 PAGIT-related guidelines and decision criteria

There was strong support among project participants for the adoption of the PAGIT Framework, and BSI was seen as one body that could take a major role in its application, leading to more proactive involvement of standards in regulatory systems, particularly for the most innovative technologies. It could also have a major role in supporting the adaptation of UK regulatory systems to address the implications of the Brexit decision without damaging future international trading prospects.

The novelty and value of this approach resides in its ability to manage the systemic interactions across different industry sectors at different stages in development of an innovative technology, with different elements of regulatory systems, involving different stakeholder constituencies. If the PAGIT Framework could succeed in supporting effective management of these interactions, even to a modest degree, we could see a dramatic improvement in the value for money generated from public and private investment in scientific research.

We chose two particularly challenging case studies: AIMDs because of the recent adoption of a new EU Regulation and the difficulties this is expected to raise for the most innovative medical devices; and the platform technologies SB and GE because of their potentially very wide range of innovative applications, the existence of dysfunctional regulatory systems in some areas, and their ability to lead to new innovative sectors and value chains or to have disruptive impacts in existing value chains.

The use of the concepts of disruptive and incremental innovation as the basis for initial decisions on whether and how an innovation should be regulated, the process of regulatory capture, is also novel.

7.2 Incremental innovation

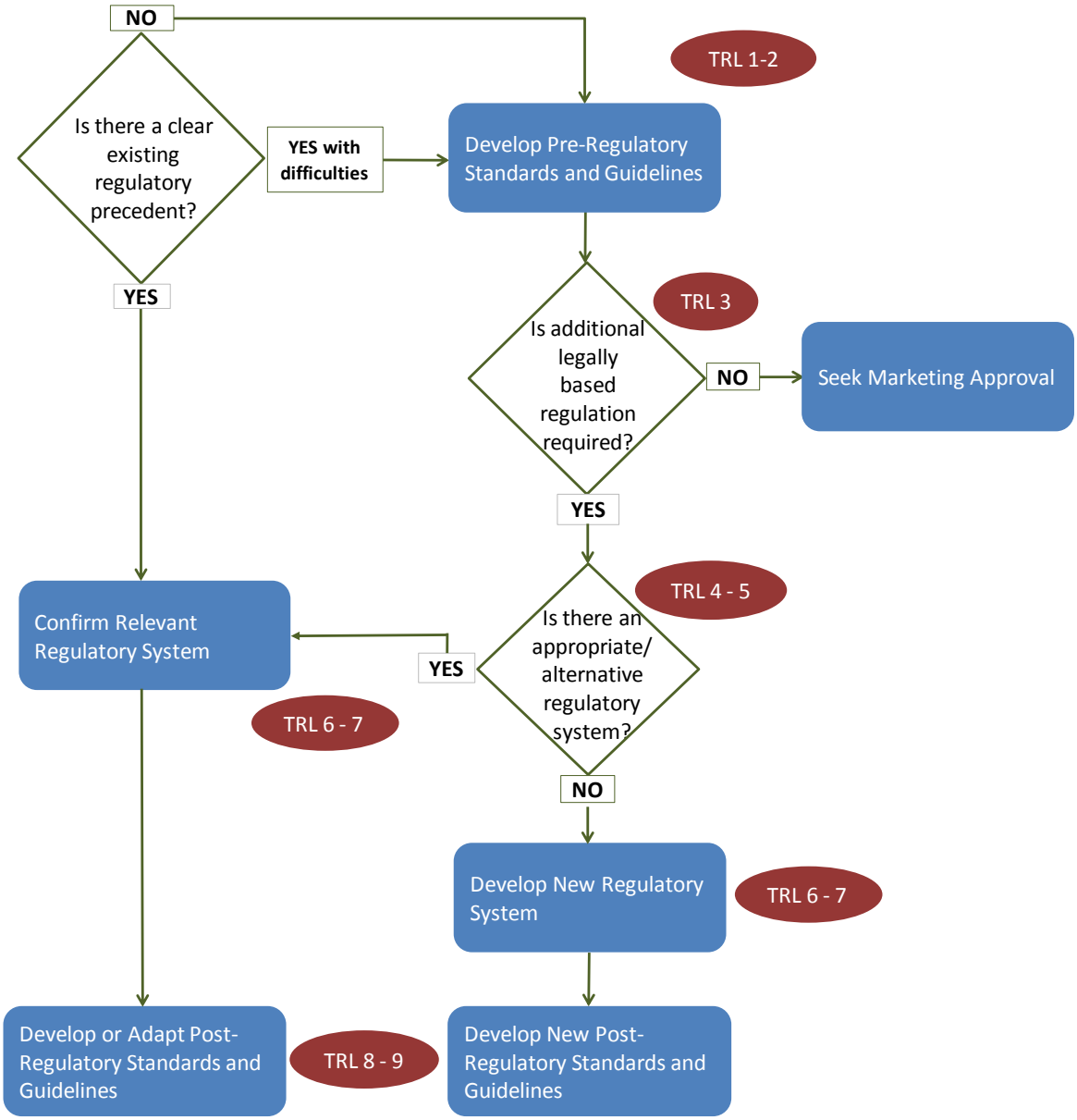
Most innovative developments can be classed as incremental, with an assumed regulatory precedent to be applied at TRLs 5 – 6 and beyond. Where requirements of the regulatory system have a disproportionate impact on development of the innovation, this can be addressed by adaptation of post-regulatory standards and guidelines (Figure 5).

As regulatory systems are routinely applied to incremental innovations, interactions between regulators and innovators are often in the form of advice from regulators on how to adapt a non-routine innovation to the needs of the regulatory system and only rarely, as proposed here, considering how to adapt the regulatory system to the needs of the innovation. The PAGIT Framework could make a difference by encouraging regulators to be more open to regulatory adaptation, by changing post-regulatory standards and guidelines in order to meet the innovation, proportionality and adaptation principles. However, regulators will remain the legally-based authority with jurisdiction over a specific area of human activity.

It is possible that an innovation initially classed as incremental will be found on closer inspection to have elements of disruption for the business models of some incumbent companies. Where this cannot be dealt with through adaptation of post-regulatory standards and guidelines, the development of pre-regulatory standards and guidelines may

be helpful as a guide to the choice of the most appropriate regulatory precedent (for example in some developments of SB and GE in crops and in industrial biotechnology).

Figure 5. Using the PAGIT Framework for incremental or disruptive innovation



7.3 Disruptive innovation

Given the policy emphasis on the importance of disruptive innovation to the national economy, there is a tendency among innovators to over-claim disruptive status for new developments, either from a simplistic understanding of the concept or as a tactic to attract investment. Disruptive innovation requires a more strategic approach to the choice of regulatory system based on the capacity of existing industry sectors (or an entirely new sector) to deliver the innovation and of course to meet expected standards of safety, quality and efficacy.

The most difficult cases will be those where there is no obvious regulatory precedent, potentially requiring a novel regulatory approach. This more complex decision making process will be justified by the benefits of enabling a greater number of disruptive innovations with related societal and economic benefits to reach a market place and to contribute to the economy. The proposal is that, during TRLs 1 – 3, there should be open discussion between regulators and innovators on the following questions:

- To what extent is the innovation disruptive of existing industry sector business models?
- For which industry sector would it be least disruptive?
- What is the regulatory system pertaining to that sector?

The answers to those questions lead into the decision process outlined in Figure 5, starting from the question about the existence of an uncontested regulatory precedent.

The most straightforward case is that where an innovation could potentially be developed by more than one industry sector, with different degrees of disruption of business models in each case. Choice of the regulatory system that applies to the sector for which the innovation would-be least disruptive could move that innovation into the incremental category for that sector, requiring post-regulatory adaptation of guidelines and standards to ensure proportionality.

The innovation may be clearly disruptive of the business models of several different sectors, with good reasons why it is unlikely to be developed successfully by any of them. The most viable option may be for new business models to be developed by new companies, probably SMEs, with the potential to lead to the emergence of an entirely new business sector. Likewise, there may be one or more regulatory options but for a number of reasons it may not be straightforward to apply any of them to the innovative technology; or there may be no clear regulatory precedent. In such cases, at TRLs 1 – 5, standards bodies and regulators can collaborate with industry and other stakeholders on the development of pre-regulatory standards and guidelines to ensure the safe and effective development of the technology in its early stages. There are then three possible regulatory choices:

(i) There is no justification for a legally-based regulatory system for the technology in question, beyond further adaptation of the pre-regulatory standards and guidelines already developed at TRLs 1 – 5. It may also be possible to subdivide the technology area so that only some products receive additional regulatory oversight beyond pre-regulatory guidelines as for example in the SB and GE case study.

(ii) There is a need for a legally based regulatory system for the technology and the development of pre-regulatory standards and guidelines has opened up the possibility of applying an existing regulatory system. Following that regulatory choice is likely to expose a need for considerable adaptation to ensure that the post-regulatory standards and guidelines are proportionate to the properties of the new technology.

(iii) If, even after further development of pre-regulatory standards and guidelines no possible regulatory precedent has emerged, then regulators will need to consider whether a new regulatory system with associated post regulatory standards and guidelines should and can be developed.

There is a potential for business and sectoral economic rivalries to lead to attempts to influence these proposed shifts of sectoral ‘ownership’ of an innovative development, mediated through choice of regulatory system. One example of a so-far successful attempt

to manage such a situation is the regulation of FinTech (one of the case studies in the first PAGIT project report[73]). Similar regulatory challenges are arising in the application of the innovative blockchain technology to big data related innovation in medical fields, and in the context of driverless vehicles.

As described above, for disruptive innovation there will be an initial period where the relationship between innovators and regulators is one of dialogue and mutual accommodation, up to the point (TRL 5 – 6) where a decision has been made about which regulatory system should be adopted. From that point on the relationship will be similar to that described for incremental innovation.

7.4 The regulatory case study examples

The following summaries demonstrate how the above guidelines and decision criteria could be applied to the two case studies, and the implications and benefits of the PAGIT Framework.

AIMDs:

For AIMDs, no questions are raised about their regulatory category. They are clearly medical devices and are likely to be developed by a medical device sector that currently includes a spread of large and small companies, most of whom are not highly innovative. This would put them clearly in the incremental category with a clear choice of regulatory system for a company at TRL 5 – 6.

This does not mean that companies and innovators should only begin thinking about regulation at that point. From TRL 1, they should be thinking about the nature of the regulatory system they will meet and its implications for the future viability of the intended product. They should ensure that the research-related choices they make do not cause unnecessary problems for the innovation at TRLs 6 and beyond. This approach is currently being adopted in two UK Research Council funded projects[74]

The unusual feature of this case is the new EU Regulation in place from early 2017, and the associated uncertainty about the nature of future post-regulatory standards and guidelines. This is causing difficulties for companies but it also provides an opportunity for the regulators and standards bodies to engage with innovators by considering how to adapt post-regulatory standards and guidelines to the needs of the innovation.

AIMDs are the most innovative category of medical device, often described as 'high-risk', but also potentially very 'high benefit'. The sector is on the threshold of a major step forward in innovation capacity, building on scientific advances in biotechnology, electronic engineering, information technology, materials science, big data and communications. Extracting maximum benefit from these developments will require a flourishing SME sector alongside, but independent from, a group of large multinational companies. Creative adaptation of post-market standards and guidelines with the needs of non-standard innovations in mind, may be necessary to ensure that the disappearance of the vitally

[73] 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,* pp 17-18. https://www.bsigroup.com/en-GB/about-bsi/uk-national-standards-body/BIS-Exploring-new-areas-with-government-funding/Governanceofinnovativetechnologies/

[74] http://www.impact.eng.ed.ac.uk/; http://www.synbio.ed.ac.uk/

important independent small companies in this sector is not the most likely outcome of the EU MD Regulation.

SB and GE:

Innovation based on SB and GE was proposed at the beginning of the project as an example of disruptive innovation. However, application of the PAGIT Framework has led to a more nuanced understanding of where innovation can usefully be re-considered as incremental and where the disruptive business models being developed by SMEs may require either the development of new regulatory approaches or major adaptation of existing regulatory systems (Figure 5).

For future crop-related developments in large scale commodity crops that are developed by a limited number of multinational companies, innovation in both SB and GE is likely to be incremental in its influence on current business models but, as noted in Section 3.3, these companies are unlikely to undertake the most disruptive innovations. For these companies, the EU regulatory system for GM crops would be an unproblematic choice except for the serious politicisation of the final decision on market authorisation. The Brexit decision makes it possible (but not certain) that the UK could remove that political influence and support SB and GE-related innovation in large companies developing commodity crops for non-EU countries.

For both crop-related and industrial biotechnology developments of SB and GE, there is the potential for development of disruptive innovation by SMEs with new business models and new potential markets. These new business models could lead to new value chains and new industry sectors and could eventually challenge those of incumbent multinational companies. For disruptive innovation as in these two cases, the PAGIT Framework would lead to consideration of which regulatory system is most proportionate and potentially adaptive to the needs of the innovative technology.

- For industrial biotechnology developments, the EU Contained Use Regulations are currently seen as fit-for-purpose but as the technologies evolve it will be important to be alert to any demand or opportunity to adapt the related post-regulatory standards and guidelines to facilitate innovation while retaining expected standards for safety, quality and efficacy.
- For crop-related developments, unlike industrial biotechnology, the EU regulatory system for GMOs, even without the political overlay, will be prohibitively expensive and time consuming for an SME. Again, following the PAGIT Framework, the suggested approach is to develop pre-regulatory standards and guidelines at TRLs 1 – 5, and then to consider the development of a new regulatory system proportionate to the properties and needs of SB and GE, including the option that there is no requirement for further legally based regulatory oversight beyond pre-regulatory standards and guidelines.

7.5 Guidelines for regulators, standards developers and policy makers in meeting the innovation principle

As noted at the beginning of this report, compliance with the three principles – innovation, proportionality and adaptation – is now being required of regulators to a greater extent than has been the case in the past. There has also been ongoing revision of societal expectations of regulators in general, for example by the OECD (Table 2). Also, in the UK, the

Department of Business Innovation and Skills has imposed a 'growth duty' for non-economic regulators to ensure that they take account of the economic consequences of their actions[75].

Table 2. OECD Principles of Good Regulation[76]

i)	Serve clearly identified policy goals, and be effective in achieving those goals
ii)	Have a sound legal and empirical basis
iii)	Produce benefits that justify costs, considering the distribution of effects across society and taking economic, environmental and social effects into account
iv)	Minimise costs and market distortions
v)	Promote innovation through market incentives and goal-based approaches
vi)	Be clear, simple and practical for users
vii)	Be consistent with other regulations and policies
viii)	Be compatible as far as possible with competition, trade and investment-facilitating principles at domestic and international levels

Giving guidance to regulators dealing with innovative technologies will require additional elements related to compliance with the three principles, innovation, proportionality and adaptation. Building on the PAGIT Framework, the following guidelines and decision criteria are proposed for regulators, policy makers and standards bodies (Figures 3 and 5).

1. For incremental innovation where there is a clear uncontested regulatory choice, the Principles of Proportionality and Adaptation can generally be dealt with through revision (where needed) of post-regulatory standards and guidelines at TRLs 7-9.
2. Where an innovation is perceived to be disruptive, regulators and standards bodies should build on a staged approach, beginning with the development of pre-regulatory standards and guidelines (TRLs 1-5) to provide a better-informed basis for the decision on the appropriate legally based regulatory precedent (TRL 6).
3. In deciding on a future regulatory system for a potentially disruptive innovation, consider first the regulatory system in operation for the sector for which the technology will be least disruptive[77].
4. The most disruptive innovations (and hence the most challenging to regulate and the most likely to generate citizen concerns) are those that disrupt an existing market or create a radically new market, or both.

[75] UK Department for Business, Innovation and Skills (2013) *Government Response – Non-economic regulators: duty to have regard to growth.* Better Regulation Delivery Office, July, 2013, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/263265/13-1018-growth-consultation-response.pdf

[76] OECD (2014) *The Governance of Regulators, OECD Best Practice Principles for Regulatory Policy*, OECD Publishing. http://dx.doi.org/10.1787/9789264209015-en

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

5. Applying the revised PAGIT Framework to an innovative technology across all TRLs, 1-9 can, beyond considerations of its disruptive nature, also be required where the regulatory system that is the most logical precedent for an innovation is seriously disproportionate, e.g. the EU regulatory systems for GM crops.
6. As in the AIMDs case study, there may be some circumstances where an innovation classed as incremental by comparison with pre-existing technologies is disproportionately challenged by the regulatory system, potentially requiring future adaptation through pre-regulatory standards and guidelines.

An important factor pushing regulators to make early decisions on the future regulation of innovative technologies is the requirement of venture capital and other potential financial investors to have a clear idea of how the technology will be regulated and hence how long it will take and how much it will cost. However, the choice of a regulatory system which needlessly curtails the innovative potential of a new technology will also be a major threat to the value of the investment.

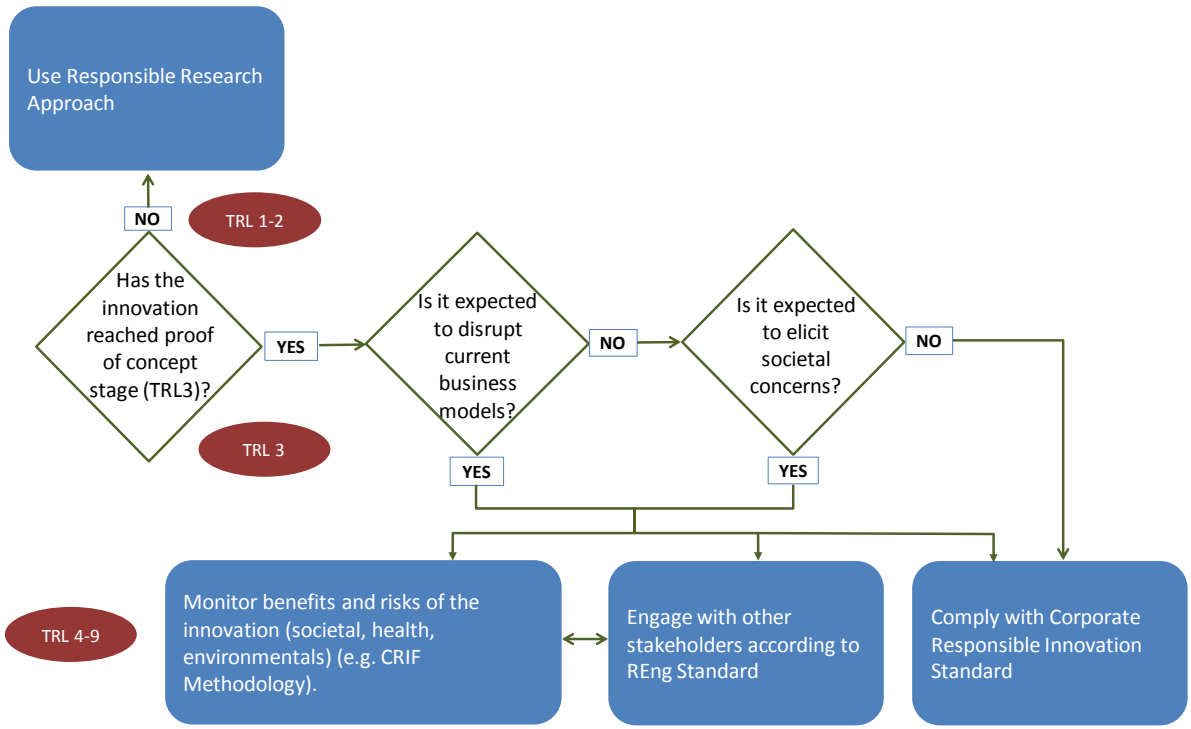
7.6 Developing a Framework Responsibility Standard

Project participants were generally interested in, and supportive of, the suggestion that standards could play an important role in delivering responsible innovation and that the development of these standards could have a role in defining the concept of RI. The following proposals for the nature and content of such a standard are tentative and will require further discussion and elaboration with stakeholders as part of any future standards development process.

As outlined in Figure 6, the proposed approach to RI would incorporate standards in a variety of roles. At TRLs 1 and 2, when the innovation is at the basic research stages it would be considered under the RR heading (not discussed in detail in this project). Beyond 'proof of concept' at TRL 3, the PAGIT Framework addresses the innovation principle by thinking first about whether the innovation is likely to be disruptive or incremental, for whom, to what extent and at what point in the relevant value chains. If it is not disruptive and is not likely to elicit societal concerns for other reasons, company/innovator compliance with the CRI Standard, implemented through the company's standard operating procedures, would be sufficient in most cases to meet the responsibility requirement, in keeping with the principle of proportionality. (Understanding whether and to what extent an innovation is likely to elicit societal concerns is part of the RR process and would be addressed at that stage.)

From TRL3 through to TRL9, where an innovation is expected to have important elements of disruption at some points in relevant value chains, a company would be expected to consider in more detail the nature of the innovation itself and its benefits and risks. Section 6.5.1 (Table 1) suggests one approach to company delivery on these expectations to take account of project- or product-specific aspects of an innovation. Based on the Consolidated RI Framework, combining the Technology Strategy Board (TSB) RI approach and the UK Research Councils AREA requirements (anticipate, reflect, engage and act), a company could be expected to continue monitoring these aspects of the innovation through to TRL9, given the extent to which disruptive innovation can experience major changes in properties and outcomes during the later TRLs.

Figure 6. Using the PAGIT Responsibility Standard



The 'engage' component of the AREA requirements would be implemented through the proposed REng Standard (Section 6.5.2). Ongoing stakeholder engagement may be beyond the resources of some companies and although this could be carried out on a company-by-company basis, it may be preferable for it to be carried out by an impartial body on behalf of an industry sector or group of companies.

7.7 Brexit context

The PAGIT Framework, with its commitment to the three principles (innovation, proportionality and adaptation), its novel emphasis on the disruptive potential of an innovation, and its overall systemic approach, could make a significant contribution to the UK government's desire to lead internationally in developing a regulatory test-bed for innovative technologies internationally. The Brexit process, transferring EU regulatory systems to UK jurisdiction, could provide the platform for implementation of these novel ideas, enabling the UK to participate more proactively in international governance systems and to be a more significant player, for example, in the global bioeconomy.

Of the two case studies considered in this report, AIMDs are an example where the best interests of the UK would be served by mirroring the requirements of the EU legislation in order to maintain access for UK companies to EU markets. However, there may be opportunities within these constraints to adapt post-regulatory standards and guidelines to make them more proportionate to the needs of innovative technologies but retaining 'regulatory equivalence' with the EU system.

SB and GE regulation is a more complex case. For industrial biotechnology a regulatory approach similar to that for AIMDs is likely to be in the UK's best economic interests. However, where there is to be a planned, uncontained use of a living organism, the interests

of the UK economy may be best served by adopting a different regulatory system from that of the EU, to bring us more into line with other major international trading blocks.

7.8 Next steps

The outcomes of this project have reinforced our view that standards of various types could play an important role in meeting the urgent need to make our regulatory and governance systems more adaptive and proportionate to the needs of innovative technologies. Analysis of the issues raised by the three case studies has supported the proposal to base the initial choice of regulatory approach for an innovative technology on the extent to which it can be considered to be incremental or disruptive of incumbent industry business models. As we have shown, this is not always a straightforward choice, but the process of understanding the nature and location of the disruption can have a useful role in delivering the optimal choice of regulatory system.

A particularly important aspect of the PAGIT approach is its ability to clarify several aspects of decision making for innovating companies.

- It brings in an emphasis on the innovative technology itself and the importance of tailoring the regulatory system to the needs of the technology, rather than finding ways to make the technology fit the requirements of a sometimes arbitrarily chosen regulatory system.
- It helps industry to take a more active role in, and to manage the process of, regulatory adaptation and compliance, in particular for the rare but important occasions when the innovation promises to be disruptive.
- It clarifies and places appropriate boundaries on RI related expectations of companies' behaviour, and proposes a more proportionate distribution of the responsibility requirement across all stakeholders.

The following further developments are proposed:

(i) Application of the PAGIT Framework to imminent decisions in the UK on future regulation of SB and GE, building on the case study conducted here;

(ii) Immediate moves within BSI towards development of a Framework Responsibility Standard, with the elements proposed here;

(iii) Continued involvement of BSI in the development of post-regulatory standards and guidelines for AIMDs, being alert to any opportunities that arise over the next three years to adapt these instruments to the needs of the most innovative AIMDs;

(iv) Development of further case studies on potentially disruptive technologies to enable wider uptake of the approach.

(v) Development of a detailed analysis of the opportunities to use the PAGIT approach to optimise the UK's future regulatory systems for innovative technologies, including in the context of the Brexit decision.

Annex 1. Definitions

Sections 1 – 3

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.

Publicly Available Specification is a document that standardizes elements of a product, service or process, usually commissioned by industry leaders – be they individual companies, SMEs, trade associations or government departments. It helps to set the agenda for a sector, helps it to work with regulators, and to set an agreed level of good practice or

quality or establish trust in an innovative product or service (http://shop.bsigroup.com/Navigate-by/PAS/).

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).

Section 4

Active Implantable Medical Device (AIMD): Directive 90/385/EEC defines an active implantable medical device as "any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure". As one of the highest risk categories of device, they are subject to rigorous regulatory controls both pre- and post-market (https://www.bsigroup.com/en-GB/medical-devices/technologies/aimd/.

Section 5

Synthetic biology. The currently agreed EU definition is “the application of science, technology and engineering to facilitate and accelerate the design, manufacture and/or modification of genetic materials in living organisms.” (http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_044.pdf).

The UK Synthetic Biology Roadmap describes it as “the design and engineering of biologically based parts, novel devices and systems as well as the redesign of existing, natural biological systems …. [with] the potential to deliver important new applications and improve existing industrial processes – resulting in economic growth and job creation” (http://www.rcuk.ac.uk/publications/reports/syntheticbiologyroadmap/).

Gene Editing is a process in which DNA is inserted, deleted or replaced in the genome of an organism using engineered nucleases, or "molecular scissors", resulting in targeted mutations ('edits'). (The process also occurs naturally.) Techniques used include zinc finger nucleases (ZFNs), transcription activator-like effector-based nucleases (TALENs), and the CRISPR system (clustered regularly-interspaced short palindromic repeats), e.g. CRISPR–Cas9, delivering the CAS9 protein. (https://en.wikipedia.org/wiki/Genome_editing).

Section 6

Responsible Research & Innovation (RRI): The European Commission 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.” (https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation).

Annex 2. Types of standards developed by the BSI[78]

BSI full consensus documents (standards) are prepared by a committee and involve broad consultation as part of the approval system. They take some time to produce and for the agreement to go through public review: 12–18 months for a national standard and up to 3 years for an international one.

The following types of full consensus standards are listed by BSI:

- Specification – outlining performance and/or design and/or service requirements that need wide consensus;
- Method – focusing on the way products and materials are tested or the way they are specified;
- Vocabulary – defining terms used in a sector or technology;
- Code of Practice (CoP) – guidance and recommended options from outline design to workmanship and safe practice;
- Guide – general guidance with recommendations and background information, less specific and more discursive than a code of practice.

BSI also develops related publications or partial consensus documents that are useful for fast-changing technology sectors where it may be important to agree on a technical solution and publish it quickly before going through the checks and balances needed for a full consensus standard. The following documents are examples of partial consensus documents:

- PAS – a sponsored standard developed quickly (within 12 months) without requiring full consensus; it can be detailed and solution-specific;
- Framework Standard – voluntary consensus standards, providing a stimulus for innovation through shaping best practice[79]. (Steedman, 2013).

A more recent development is the creation of standards covering the principles required for good business practice, such as BS ISO 26000, *Guidance on corporate social responsibility*, sometimes described as 'aspirational standards'.

[78] BSI (2009) The BSI guide to standardisation – Section 1: Working with British Standards, Part 5. What are the different types of standards? Available from: http://www.bsigroup.com/Documents/standards/guide-to-standards/BSI-Guide-to-standards-1-5-standards-types-BSI-UK-EN.pdf

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