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The pagit framework

Its role in the governance of UK technologies to drive greater innovation

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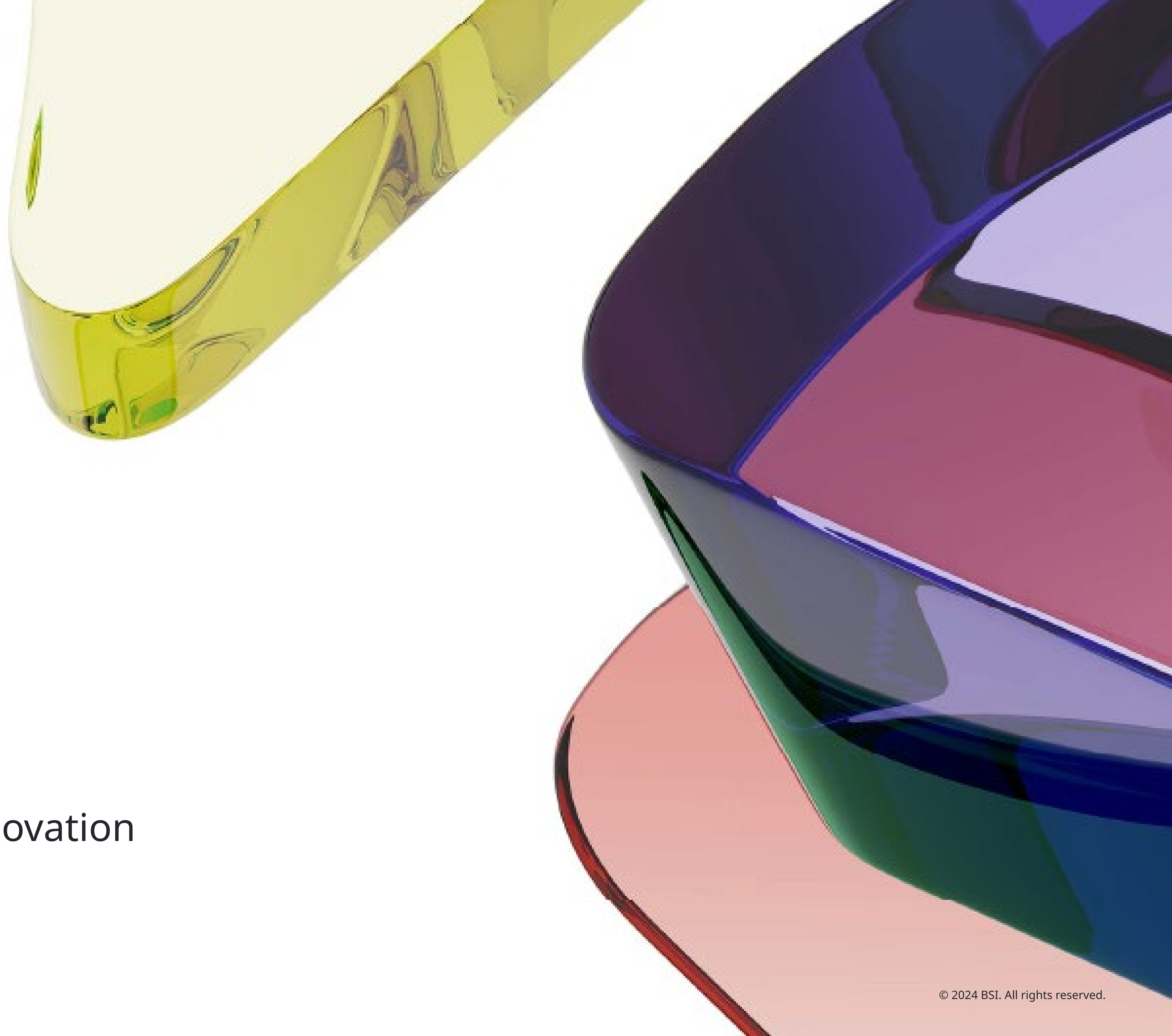

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Executive Summary

Introduction

Innovation has a widely acknowledged role to play in the growth of economies and in delivering policies to address climate change and biodiversity loss. How we choose to govern or regulate innovative products and services will determine which reach an end market, the industry sectors best able to develop them, and the future shape of these sectors (including the extent of participation by SMEs, and the territories which will benefit most from them).

This report charts the progress made over the past 30 years in understanding these interactions and in using that understanding to support better governance decision making by companies, regulators and standards bodies through the use of a framework called the Proportionate and Adaptive Governance of Innovative Technologies (PAGIT).

Taking innovators' perspectives: the STRATIS model

An interdisciplinary programme of academic research that began in the 1980s has built a picture of emerging innovative technologies, mainly in life sciences, focusing on business models and value chains and their interactions with regulatory systems at different stages of development to deliver a novel product or service to the market.
A systemic model, known as the Strategic Analysis of Advanced Technology Innovation Systems (STRATIS) (see sections 3.1 and 3.2), looks at these interactions from innovators' perspectives and uses the Technology Readiness Level (TRL) scale to identify sequential stages of product development.

Such analysis takes into account the following factors:

- How our understanding of the properties, risks, and benefits of an innovation change over time as it moves through TRLs, opening up or closing down future opportunities and changing the related governance questions and challenges.
- A product or service will often go through a series of B2B transactions as it progresses through the TRLs, with each company having a different business model, innovation challenges, and regulatory or governance demands.
- Innovation that is incremental will: not lead to sectoral transformations, fit well with a firm's current business model, generate competitive advantage, contribute to the economy through more efficient use of resources or elimination of wasteful or environmentally damaging practices, likely have a clear pre-existing regulatory framework in place, and be less likely to lead to stakeholder concerns.
- Innovation that is disruptive will: involve discontinuities in innovation pathways, require new areas of research and development, create new modes of production and markets, lead to sectoral transformations and the displacement of incumbent companies, and create entirely new sectors with significant societal and economic benefits, likely not benefit from a pre-existing business model on which to build and need to create new value chains, or new roles in existing value chains. Further, there may be no obvious regulatory precedent to govern potential human and environmental safety issues arising from disruptive innovations and in some cases, there may be significant stakeholder concerns that will need to be addressed through governance. Today's disruptively innovative technologies include Engineering Biology, Quantum Technologies, and Artificial Intelligence (AI).

The research that helped enable understanding of the interactions between these factors, specifically the Strategic Analysis of Advanced Technology Innovation Systems (STRATIS), formed the basis of the PAGIT Framework.

Taking regulators' and policy makers' perspectives: the PAGIT framework

The PAGIT Framework is intended to support decision makers to govern the development of innovative technologies as they are translated along a value chain. It aims to enable the development of innovative products and services with societal, environmental, health-related and economic benefits, to high standards of safety, quality and efficacy, on a faster, more equitable, and more certain basis.

It arose from the experience of seeing attempts to commercialise innovative developments fail because of confounding, governance-related factors that either delayed decision-making or created barriers. The problem was most serious for disruptive innovations with most to offer in terms of societal, environmental, health, and economic benefits. Given the amount of public and commercial funding that had been committed to supporting innovation in these domains, these failures were also a significant waste of resources.

In response, the Framework uncovers ways to avoid problematic governance decisions in the first place or to adapt existing governance approaches - or create new ones - so that they are more proportionate and adaptive to the needs of innovative technologies. It identifies the following factors for regulatory and policy decision makers to consider:

Where/how we 'capture' a new class of product within a governance system

The answer to this question will determine whether new industries can coalesce around an innovative technology area, define their future shape, and determine the scale of their contribution to economies. Pressure from industry, policy makers, regulators and societal lobby groups have led to inappropriate choices of regulatory approaches in the past. A poor choice of regulatory precedent (or delay in making such a choice through lack of a decision framework) is by far the most common reason for issues to arise.

Disruptive innovation sometimes faces the decision whether to regulate on the basis of the technology or process itself (such as in the cases of regulating Quantum Technologies and Engineering Biology) as an additional - often costly - imposition, prior to further regulation on the basis of the properties of specific classes of products and services. The recommendation is that it is generally advisable to avoid 'process-based' governance decisions altogether; instead, to regulate on the basis of the properties of specific classes of product to deliver the necessary levels of safety, quality, and efficacy associated with the innovation.

The TRL scale

This scale is used to guide the timing and sequencing of governance-related decisions in the process of transitioning an innovative technology from the proof-of-concept stage to a commercial product or service. The scale is relevant to decisions on the choice of regulatory precedent to apply to a new technology, particularly for a disruptive innovation and can help decision makers avoid resorting prematurely to legally-based regulation (i.e. 'hard law') before TRL 6 which can then be difficult to adapt to greater understanding of an innovation's properties at later TRLs. Standards and guidelines are usually more beneficial tools to govern the early development stages of an innovative product or service at TRLs 4 – 5 while further investigations are conducted to understand the likely future properties of the product or service and its governance requirements. This enables the choice of governance approach at TRL 6 to be based on, and more proportionate to, the properties of the innovative product or service, avoiding the need to adapt it later (which can be time-consuming and bureaucratic).

Distinguishing between disruptive and incremental innovation

As noted in the 'Innovators' Perspectives' section above, incremental innovation - with a predictable and established governance pathway - usually only requires governance-related attention at TRL 6 and beyond. For disruptive innovation, its developers need to consider expected governance precedents at all stages from TRL 1 onwards. Disruptive innovations may have very different properties from previous generations of technologies for which today's regulatory systems were designed and this is where many innovative developments are stalled. However, the PAGIT Framework identifies standards and guidance (i.e. 'soft law') as useful tools in enabling adaptation of current legally-based regulatory approaches to meet the needs of 21st century innovative technologies.

The role of standards (soft law) instead of, or in support of, legally-based regulatory approaches (hard law).

The PAGIT report makes several recommendations on the relative role of standards, guidelines, and regulations depending on the stage of development of the innovation, the extent to which it is disruptive or incremental, and for which companies at which stages of technological development it will be most disruptive. The utility of standards to the governance of innovation lies in their diversity and ability to cope with a broad range of circumstances (covering products, services, manufacturing and organisational behaviour), their adaptability in the face of a rapidly evolving technology landscape, and their capacity to achieve consensus across a broad range of stakeholders. An approach that balances these influences is likely to deliver more optimal outcomes for both disruptive and incremental innovation.

The role of technological innovation in regulatory adaptation.

An important tool, worthy of greater attention in future, is the deployment of technological innovation itself to detect and eliminate - or minimise - specific hazards in a product or service, rather than adopting governance instruments that may restrict its future development and use. Where those involved with a disruptive innovation pay early attention to its likely future regulatory pathway, they may be able to adapt its attributes to guide it towards the most appropriate form of governance.

Supporting Responsible Innovation (RI).

Based on recommendations in the PAGIT Reports, Innovate UK funded BSI to develop a Publicly Available Specification (PAS) on RI (PAS 440). The PAS provides companies - across all innovative sectors - with support: first, to assure themselves that they are behaving responsibly and, second, to enable them to demonstrate their responsible behaviour to stakeholders.

More specifically, PAS 440 has the following attributes:

- It distinguishes between (a) routine, company-wide aspects of responsibility, to be addressed within an organisation's standard operating procedures and applicable to all companies, and (b) innovation-specific aspects, applicable to companies actively involved in innovation;
- It distinguishes between incremental and disruptive innovation;
- It provides companies with a framework by which to balance the potential benefits and harms of an innovative development and, if necessary, to take action to maximise the benefits and/or minimise the harms;
- It recognises that what constitutes responsible behaviour will vary as an innovation progresses along a value chain from proof-of-concept stage to market availability;
- The recognition that stakeholder engagement is an important part of RI, particularly for disruptive innovations and any others that are potentially contentious;
- It provides guidance for companies when engaging with stakeholders, which features a more balanced consideration of the potentially diverging interests and views of different stakeholders;
- It links RI to meeting the requirements of net zero government policies and the UN's Sustainable Development Goals.

The Contribution of the PAGIT Framework to the UK Government's Future Regulation Agenda

Better governance decisions about innovative technologies, will help the UK government's aspiration to lead the world in developing pro-innovation regulation and to deliver its climate change and biodiversity-related policies.

The value of the PAGIT Framework lies in its ability to manage systemic interactions across industry sectors at different TRLs, with different governance-related requirements, and involving different stakeholder constituencies. It provides actors with guidance on which elements are relevant to particular governance decisions and how PAGIT-related insights could guide the governance of products as they pass along a value chain. It is intended to be applied in a flexible way, focusing on the elements that are most relevant to a particular decision. Its adoption opens up the potential for a significant improvement in the efficiency of governance approaches and the speed and cost effectiveness of regulatory decisions. This could lead to an increase in the number of UK research projects that deliver successful innovations to the marketplace, with a corresponding increase in the value for money from public and commercial investment in scientific research.

The Framework played an important role in the recent evolution of UK governance approaches through the White Paper on Regulation for the Fourth Industrial Revolution that led to the creation of the Regulatory Horizons Council (RHC) in 2019. This independent expert committee identifies technological innovations with high potential benefit for the UK economy and society, and provides government with impartial, expert advice on the regulatory reform required to support their rapid and safe introduction.

Applications of the PAGIT Framework

Regulatory Horizon Council (RHC) Reports
Two RHC reports provide examples of the application of the PAGIT Framework, more specifically:

RHC's Genetic Technologies Report included the following observations:

1. A governance system based on the technology used to develop the products and services would negatively impact innovation, and that the focus should be on the properties of the final products, including their benefits and risks.
2. Data related requirements in governance systems should be proportionate to the nature and scale of the product's potential risks.
3. Governance systems should include within them consideration of a technology's benefits, particularly those related to meeting net zero and biodiversity-related goals.
4. Application of relevant elements of the PAGIT Framework could deliver a more effectively targeted, cost-effective governance system for these technologies in the UK more quickly, and in keeping withinternational developments

RHC's Regulating Quantum Technology Applications Report focused mainly on available products in computing, timing, sensing and imaging, and included the following observations:

1. The PAGIT Framework can be applied to Quantum Technology-related innovation, building on its initial development in life sciences.
2. The development of application-specific (i.e. product-based) regulatory frameworks that are "adaptable and proportionate to the properties of individual innovations and their stage of development" are favoured.
3. Behavioural standards, including an RI standard, should be adopted to ensure effective governance of quantum products without prematurely resorting to legally-based regulation.
4. There is a need, amongst both regulators and innovators, for a better understanding of the future role to be played by pre-regulatory and post-regulatory standards and guidelines in the future governance of quantum technology developments, both nationally and internationally.
5. RI features in several of the report's recommendations, including in the development of behavioural standards, to ensure effective governance of quantum products without prematurely resorting to legally-based regulation, to mitigate current and future risks, and to foster public trust in the technology.

In addition to the RHC reports, the following case studies illustrate further uses of the PAGIT Framework:

Industrial biotechnology and the manufacture of high value chemical intermediates

This case study is based on a project which looked at how analysis of business models and value chains, linked to an understanding of the disruptive potential of innovative technologies, can be helpful in guiding policy decisions on their governance. It revealed the following insights:

i. An innovation that is disruptive of the business model of one industry sector can be incremental for another; and

ii. An innovation can be disruptive for some sectors/ business models contributing to an overall value chain, whilst only incremental for others.

The value chain for the manufacturing of high value chemical intermediates involved four types of companies, specifically: synthetic biology platform support companies; specialty chemicals manufacturing companies; formulators; and retailers (supermarkets and other retail outlets). The report suggested that innovative engineering biology developments were disruptive of the business models of the first two (upstream) sectors, but only incremental for the formulators and retailers. Further, that the latter could benefit financially from selling a more environmentally sustainable product to their customers, thus providing an example of how innovation could improve the competitiveness of a company without disrupting its business model.

In this case, the STRATIS approach provided understanding of how to enable disruptive innovation successfully by focusing on the interactions between innovative technology developments, their propensity to be disruptive of incumbent and future company business models, and the value chains to which they contribute.

Scottish salmon farming as part of a circular bioeconomy
This case study is based on a project which addressed mainly STRATIS-related aspects of the governance of innovation and considered what a policy ecosystem supportive of innovation would need to include to deliver the potential economic, health, and environmental benefits. It proposed focusing on quick wins, technologies that are already in the early stages of development, and the design of favourable circular economy and policy/governance environments that encourage the prompt identification and adoption of relevant technologies.

Policy recommendations included the need to incentivise feed producers to incorporate innovative ingredients in their feed formulations, consider the whole innovation landscape and interactions between technologies, policies, governance/regulations, and markets. However, it recognised that such policy initiatives would not be sufficient on their own to deliver the required transformation of the innovation landscape but that it would require further PAGIT-style analysis of the governance systems in place for the technologies involved.

Responsible Innovation (RI) along a value chain
This case study is based on a report which detailed the implementation of 'PAS 440:2020 Responsible Innovation Guide' in the development of single celled protein (SCP) for animal feed.

The report showed that integrating RI formally along a value chain has the potential to help value chain partners (VCPs) to be more strategically aligned, to support the translation of innovative products from proof-of-concept to market, to foresee future benefits and risks, and to adapt the development of new products or technologies accordingly. This would also contribute to the identification of consumer and VCP requirements, to foresee their future benefits and risks, and to also adapt the development of new products or technologies accordingly. The whole value chain approach enabled the VCPs to better understand the properties of the SCP and its role in their business models, to better appraise its contribution to their own RI-related agendas, and to appreciate more clearly how this area of innovative animal feed development can be better supported in future.

Innovative technologies and their future governance
The UK Government's Pro-innovation Regulation of Technologies Review in 2023 referred to the need, in an age of vast technological change, for regulators to adapt their approaches to enable the safe and rapid introduction of beneficial emerging technologies at scale. To do so effectively, regulators will need to have a more nuanced understanding of innovators' perspectives and vice versa and the PAGIT Framework brings together both perspectives.

The PAGIT Framework's key recommendations (for regulators, policymakers and innovators):

i. **Choice of regulatory precedent (for regulators and policy makers)**: when selecting regulatory precedent, to avoid 'process-based' governance decisions based on the properties of the process by which the innovation has been developed; instead, 'product-based' regulation devised on the basis of the properties of specific classes of products will deliver sufficient levels of safety, quality and efficacy. Further, to consider the implications of this choice for future governance decisions and for the viability of future innovation pathways.

ii. **Use the TRL scale (for regulators, policy makers and innovators)**: to develop understanding of the relationships between companies participating in a value chain (based on their business models), and to guide the timing and direction of decisions (e.g. when choosing the regulatory precedent to apply to new innovative products).

iii. **Disruptive and incremental innovation (for regulators, policy makers and innovators)**: to understand the extent to which an innovation will be disruptive or incremental, for which companies or sectors, and at which stages of development (TRLs) it will be most disruptive.

iv. **'Soft' and 'hard' law (for regulators and policy makers)**: to avoid resorting prematurely to legally-based regulation (i.e. 'hard' law) and where possible prioritise the use of standards and guidelines as governance instruments (i.e. 'soft' law).

v. **The role of technological innovation in regulatory adaptation (for regulators, policy makers and innovators)**: to consider the deployment of technological innovation itself at an early stage in the product's development to detect and eliminate or minimise hazards in a product or service, rather than having to adopt governance instruments to do so that may restrict its future development and use.

vi. **Approach to innovation (for innovators)**: to adopt a responsible innovation approach, particularly for disruptive innovation developments.

There is general agreement that the UK's future prosperity, and its ability to meet climate change and biodiversity-related objectives, will depend on successful and rapid deployment of innovative products and services across all sectors of the economy. The PAGIT Framework could make a significant contribution to ensuring that our future governance systems support these objectives.

Chapter one

Background

This report builds on a research programme that began over twenty years ago, charting the extent to which governance systems are ill-adapted to the needs of innovative technologies, leading to abandonment of innovations that could meet pressing societal needs and loss of the creative innovation potential that could come from small companies with the ambition to develop transformative new products and services. As an example of how far governments have changed in their thinking over the past 20 years, the theme of **pro-innovation regulation** was taken up by the UK Government in 2023 in a series of reports re-affirming the links between providing support for innovation and its economic growth impacts, and governance of its environmental, health and societal impacts[1]. This report will cover the intervening period between these two states, showing how those involved moved from patchy awareness of a problem, through an understanding of the nature and scale of its impacts, to beginning to understand what could be done about it.

1 HM Government (2023) *Pro-innovation regulation of technologies review: Cross-cutting and growth duty recommendations.* https://assets.publishing.service.gov.uk/media/655cd10ad03a8d001207fdfd/_8243__GCSA_Pro_Innovation_cross_cutting_Report_PDF.pdf

The Innogen Institute's portfolio of research cases that provided evidence on how and where governance systems are having these negative effects included: diagnostic devices; drug development; initiatives to overcome antimicrobial resistance; regenerative medicine, stratified medicine and stem cell therapies; agricultural biotechnology; animal cloning; and industrial biotechnology/engineering biology[2,3,4,5,6,7,8].

2 Bruce, A., Castle, D., Gibbs, C., Tait, J. and Whitelaw, C.B.A. (2013) Novel GM animal technologies and their governance. *Transgenic Research*, Published online, 19 June, 2013, pp 1-15; (http://link.springer.com/content/pdf/10.1007%2Fs11248-013-9724-5.pdf).
3 Courtney, A., de Sousa, P., George, C., Laurie, G., and Tait, J. (2011) Balancing Open Source Stem Cell Science with Commercialisation, *Nature Biotechnology, 29(2),* Feb. 2011, 115-116.
4 Mittra, J. and Tait, J. (2012) Analysing Stratified Medicine Business Models and Value Systems: Innovation-Regulation Interactions. *New Biotechnology, 29(6),* 709-719
5 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#).
6 Tait, J. with Wield, D., Chataway, J. and Bruce. A. (2007) Health Biotechnology to 2030. Report to OECD International Futures Project, *The Bio-Economy to 2030: Designing a Policy Agenda*, OECD, Paris, pp 51; (http://www.oecd.org/dataoecd/12/10/40922867.pdf).
7 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)
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)

In the 1990s it was controversial to suggest that regulations should be adapted to meet the needs of innovative technologies. Innovators were expected to adapt their products or services to meet the requirements of the prevailing regulatory system and they generally felt that it would be unwise to challenge this assumption. Since the 1990s, researchers at the Innogen Institute have widely disseminated the evidence from their research, pointing to the need for more agile implementation and adaptation of today's regulatory and governance systems to meet the needs of innovative technologies. These ideas gradually gained acceptance in policy circles, but how to make the necessary changes remained a challenge.

This led to BSI funding two reports on the Proportionate and Adaptive Governance of Innovative Technologies (PAGIT), specifically:

1. Proportionate and adaptive governance of innovative technologies: The role of regulations, guidelines and standards (Tait and Banda, 2016)[9]
2. Proportionate and Adaptive Governance of Innovative Technologies (PAGIT): A framework to guide policy and regulatory decision making (Tait, Banda, and Watkins, 2017)[10]

This report describes the background and the research leading up to these reports, how the framework was developed and its evolution and influence since its development.

Evidence of the need for regulatory adaptation is continuing to emerge across a broad range of innovative technology areas, but particularly for innovation that is disruptive of incumbent company business models or transformative of markets but potentially delivering societally or environmentally useful products and services[11].

9 Tait, J. and Banda, G. (2016) Proportionate and Adaptive Governance of Innovative Technologies: the role of regulations, guidelines and standards. Summary Report to British Standards Institution. [https://www.bsigroup.com/localfiles/en-gb/bis/innovate%20uk%20and%20emerging%20technologies/summary%20report%20-%20adaptive%20governance%20-%20web.pdf]

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

11 https://www.gov.uk/government/groups/regulatory-horizons-council-rhc#reports

1.1 Evidence supporting the need for regulatory adaptation

Before governance-related change can take place, there needs to be a general recognition of the problem, and the Innogen Institute research programme since 2002 has aimed to demonstrate where such problems exist, to chart their impact, and to propose how they might be mitigated. The following insights were gleaned from the research conducted by the Innogen Centre, now the Innogen Institute, from 2002 up to the present day (www.innogen.ac.uk).

Past governance choices, particularly for the most innovative technology areas have often been idiosyncratic, and reflective of a range of pressures from industry, policy makers, regulators, and societal lobby groups. As a result, governance systems in these areas became complex, rigid, time consuming and, for smaller companies, prohibitively costly. Where large companies dominate the innovation ecosystem, the research referenced above showed how incumbent companies focus their attention on incremental rather than disruptive or transformative innovation, making it very difficult for an SME to gain an independent competitive advantage based on a disruptive innovation, and how this loss of innovation potential has had a significant negative impact on the UK economy.

When important, fast-developing new technology areas have emerged, such as in the life sciences, regulators have been quick to raise questions about how they can keep pace with innovation and technological developments in order to have an effective governance system in place before new products and services arrive in the market.
This perceived urgency may have led to rushed and problematic decisions about who should be the regulator of choice and what regulatory precedent should be applied to the new developments. An important factor pushing regulators to make these early decisions is the need for 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 to develop. However, the earlier such a choice is made, the less will be known about the nature and properties of the emerging products and services, and the more likely it is that the choice of governance system may not be optimised to these properties. Rather than supporting innovative developments, many governance systems have been inadvertently curtailing their innovative potential.

On the other hand, for artificial intelligence (AI) and other information technology innovations, it has been said that governments were ill-equipped to address governance issues in the early stages of their development, leading to today’s challenges, specifically to adapt old governance systems to meet the challenges raised by new technologies or to devise new governance systems for already well-established technologies. It is therefore important that those governing new areas of innovation learn from past experience and avoid making similar mistakes.

How we choose to include or ‘capture’ new classes of products within a specific governance system will determine whether new industries can form around an innovative technology area, define their future shape, and determine the scale of their contribution to national economies. Pressures from industry, policy makers, regulators and societal lobby groups alike may have led to some inappropriate choices of regulatory precedent.

Examples from the fields of biosciences and biotechnology include:

- to regulate all genetically modified organisms (GMOs) according to the process (genetic modification (GM)) by which they were produced rather than the properties, benefits and hazards of the products themselves (EU GM Regulatory System)[12];
- to treat cell therapies as 'drugs'[13];
- to regulate biopesticides through the chemical pesticide related regulatory system[14];
- to regulate GM crops as 'a plant pest' (US regulation of GM crops)[15];
- to regulate a GM fish or cow as 'a drug' (US Regulatory system)[16, 17]; and
- to capture agriculture-related products incorporating innovative advanced biotechnology techniques on the criterion of whether the product is 'novel' for that country, only later considering the properties of the product itself (Canadian regulatory system for genetic technologies)[18].

All of the above choices have had flaws, some with very significant negative impacts on innovation in the sectors involved. These piecemeal approaches to regulation also do not lend themselves well to subsequent adaptation to use better evidence-based criteria to judge the risks and benefits of a new technology in later stages of its development, once there is more information available on its properties. Such choices also determined what evidence would be relevant to decision making and, indirectly, which sector of the economy would be able to develop the technology. For example, the fact that cell therapies were expected to go through the drugs-based clinical trials system, drove the technology strongly in the direction of being developed exclusively by the pharmaceutical industry sector. If they had been regulated as a medical device or a surgical procedure, as some were advocating at the time,[19,20] the relevant rules would have been those governing surgical procedures, implying a very different (perhaps

12 Conko, G. *et al*. (2016). A risk-based approach to the regulation of genetically engineered organisms. *Nature Biotechnology, 34(5),* 493-503.
13 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#
14 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.
15 US Congressional Research Service (2017) *Advanced Gene Editing: CRISPR-Cas9,* April 28 (2017), p21. R44824; https://fas.org/sgp/crs/misc/R44824.pdf
16 Pew Initiative on Food and Biotechnology (2001). *Guide to US Regulation of Agricultural Biotechnology Products*. https://www.pewtrusts.org/~/media/legacy/uploadedfiles/wwwpewtrustsorg/reports/food_and_biotechnology/hhsbiotech-0901pdf.pdf
17 Miller, H.I. and Hefferton, K.L. (2021) Regulators kept a fish treading water for years. *Regulation* Cato Institute) https://www.cato.org/sites/cato.org/files/2021-09/regulation-v44n3-7.pdf (Note: this article is written from the perspective of the industry affected by the regulation).
18 Smyth, S.J. (2017) Canadian regulatory perspectives on genome engineered crops. *GM Crops and Food, 8(35),* 35-43.
19 Von Tigerstrom, B. (2008) The challenges of regulating stem cell based products. *Trends in Biotechnology*, 26(12), 653-658. https://doi.org/10.1016/j.tibtech.2008.08.004.
20 Faulkner, A. *et al.* (2003) Human tissue engineered products – drugs or devices? Tackling the regulatory vacuum. *BMJ*, 326, 1159-60. https://www.york.ac.uk/res/iht/projects/l218252058/FaulknerBMJeditorial300503.pdf

more medically effective but less profitable) business model. These inconsistencies provide ample justification for seeking a new approach to the regulatory capture and overall governance of innovative technologies.

These negative impacts of disproportionate, non-adaptive approaches to regulation will also – it is reasonable to assume – undermine or negate any positive effects potentially arising from policies designed specifically to support innovation, thus creating an incentive for those designing innovation support schemes also to consider the need for the reform of regulatory/governance systems.

Many participants and observers involved in the development of innovation ecosystems in the UK and the EU have noted that some regulatory systems had become overly precautionary and disproportionate to the nature and extent of the risks presented by many technologies, were hindering international competitiveness and the development of a vibrant economy[21,22], and needed to be adapted to the needs of modern technologies. These pressures led to the adoption of the Proportionality Principle, one of five regulatory principles set out in the UK Better Regulation Task Force 'Principles of Good Regulation', to be considered when devising, implementing, enforcing and reviewing regulations[23]:

- Only intervene when necessary;
- Remedies should be appropriate to the risk posed, and costs should be identified and minimized;
- Policy solutions must be proportionate to the perceived problem or risk, and justify the compliance costs imposed – don't use a sledgehammer to crack a nut;
- All the options for achieving policy objectives must be considered – not just prescriptive regulation. Alternatives may be more effective and cheaper to apply;
- "Think small first". Regulation can have a disproportionate impact on small businesses which account for 99.8% of UK businesses;
- EC Directives should be transposed without 'gold plating';
- Enforcement regimes should be proportionate to the risk posed; and
- Enforcers should consider an educational, rather than a punitive approach where possible.

21 HM Treasury (2015) *Fixing the Foundations: creating a more prosperous nation;* Cm 9098. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/443898/Productivity_Plan_web.pdf
22 Tait, J. (2007) Systemic Interactions in Life Science Innovation. *Technology Analysis and Strategic Management*, 19(3), 257-277, May 2007.

23 https://www.rqia.org.uk/RQIA/media/RQIA/Resources/Better-Regulation-Task-Force-Principles-of-Good-Regulation.pdf

1.2 The PAGIT Framework: A new approach to the governance of UK technologies to drive greater innovation

The above developments raised the question, "How can we adapt our governance systems to facilitate innovation while still safeguarding the safety, quality and efficacy of products?" This question cannot be answered by focusing solely on legal regulation. Improved governance procedures will also be needed, involving a broader range of instruments, and giving a more influential role to standards, guidance, codes of practice, government policies, stakeholder dialogue and engagement, based on a better understanding of the interactions between innovation and governance communities. In addition, safe, responsible adaptation of governance systems will also require detailed attention to the stage of development of the technology, the extent to which the product is disruptive of the business models of incumbent companies, and for which companies in a value chain[24] it will be disruptive. The aim of such an approach is to enable the development of innovative products and services with societal, environmental, health-related and economic benefits, to high standards of safety, quality and efficacy, on a faster, more equitable and more certain basis.

In making changes like this to governance systems, it is particularly important for companies to reassure citizens and other stakeholders that their products will continue to be developed responsibly, and that any changes made to products or production systems will be in the public interest as well as meeting the needs of innovators.

These interacting factors call for a systemic framework for the governance of innovative technologies that does not rely on simplistic approaches, modifying a single parameter in a complex innovation ecosystem, while ignoring synergistic or antagonistic impacts from other ecosystem components. Our integrated governance framework links important factors influencing the success or failure of innovations, both from the perspective of innovators (see Sections 3.1 and 3.2) and of those governing innovation practices and processes (see Section 3.3), across a broad range of domains of the economy.

1.3 The relationship between 'governance' and 'regulation'

In this report, unless otherwise specified, we use the term 'governance' to include formal legal regulation ('hard law'), along with other governance approaches such as standards, guidelines, codes of practice, policies and other processes ('soft law') by which authority and influence on practices are exercised.

Where we use the term 'regulation' it is mainly to refer to the hard law component of governance approaches, but also in some cases to discriminate between governance of the safety of innovative technologies and policies designed to support innovation in technologies (without consideration of their safety). It is common practice in government documents and elsewhere simply to use the term 'regulation' when referring to any, or all, of the various types of governance instruments, thus making it difficult to stick rigidly to these distinctions.

Annex 1 provides explanations of key terms used in this report and how they are being applied.

24 See Annex 1 for definitions of 'business model' and 'value chain'.

Chapter two

Governing Innovation

2.1 The need to govern: the current UK Government's strategy

Innovation is expected to form the future basis of the UK's national prosperity. For example, the UK's Department for Science, Innovation and Technology (DSIT)'s 2023 innovation strategy, sub-titled 'leading the future by creating it'[25] includes the commitment to support businesses who want to innovate, along with consideration of how regulation can "ensure that the UK is well-placed to extract the best value from innovation". The Department for Business and Trade also issued a paper in 2023 on 'Smarter Regulation to Grow the Economy'[26], which outlined a new vision for governance based on early consideration of approaches like standards and guidance, entailing "ensuring regulation is a last resort, not a first choice", and the monitoring and evaluation of regulations to ensure that they are delivering on their aims. This paper also committed the Government to reforming existing regulations, where necessary, to reduce burdens on innovators.

Also, in 2023, a series of reports as part of HM Treasury's Pro-Innovation Regulation of Technologies review[27], led by Sir Patrick Vallance, then the Chief Scientific Adviser, and authored by his successor Dame Angela McLean, included a cross sector report along with sector specific reports on life sciences, advanced manufacturing, creative industries and digital technologies, designed to advise on how the UK can better regulate emerging technologies. A recent report by the Boston Consulting Group (BCG) referred to these initiatives and noted that, to compete with the US, EU, and China, the UK needs to "Put innovation at the centre of regulators' operations" (one of the report's three main recommendations)[28].

2.2 The need to improve governance: new regulatory principles

These changing expectations of regulators, beyond straightforward assurance of the safety, quality and efficacy of products and services, have been evolving for some time. For example, in the UK in 2013 the Department for Business Innovation and Skills (BIS) imposed a 'growth duty' for non-economic regulators to ensure that they take account of the economic consequences of their actions[29]. As part of this transition, a statement of the principles underlying any new initiative has become expected practice. For example, the OECD in 2014[30] outlined seven principles for the governance of regulators: role clarity; preventing undue influence and maintaining trust; accountability and transparency; engagement; funding; and performance evaluation (but no reference to innovation).

25 DSIT (2021, updated 2023) UK Innovation Strategy: Leading the Future by Creating It. https://assets.publishing.service.gov.uk/media/61110f2fd3bf7f04402446a8/uk-innovation-strategy.pdf
26 UK Department for Business and Trade (2023) *Smarter regulation to grow the economy.* https://www.gov.uk/government/publications/smarter-regulation-to-grow-the-economy

27 HM Treasury (2023) *Pro-innovation regulation of technologies review.* https://www.gov.uk/government/collections/pro-innovation-regulation-of-technologies-review
28 BCG (2023) *The UK must use its strengths to respond to US and EU green industrial policies – Here's how.* https://www.bcg.com/united-kingdom/centre-for-growth/insights/pro-innovation-regulation-of-green-technologies

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

Within the PAGIT Framework, the concept of a principle is interpreted as carrying the weight of **foundational values that underlie the development of a policy or governance approach and that serves as the basis for a chain of reasoning**. Four principles are seen as essential to guide the better governance of innovative technologies, specifically:

Proportionality: Any governance-related action should be proportionate to the potential risks and benefits posed by the product or service and to the potentially conflicting interests and values of different societal groups;

Adaptation: Governance frameworks should be able to adapt to the requirements of rapidly evolving technological advances, to anticipate future shifts and adjust accordingly. In this regard, standards and guidance can play an important role, being more adaptable than legally-based regulations (see Section 3);

Responsibility: Given the benefits gained from a proportionate and adaptive governance system, innovators need to demonstrate responsibility throughout the innovation trajectory, ensuring that they are adopting best practices in corporate governance and that their innovations deliver the claimed societal, health or environmental benefits in accordance with public and other stakeholder expectations; and

Balance: Effective governance of innovation will require an equilibrium between benefits and risks, between commercial viability and responsible deployment, and between diverse stakeholder needs.

In addition to delivering safety, quality, and efficacy in novel products or services, and supporting pro-innovation governance strategies, there is evidence to suggest that regulators are, or will be, increasingly required to support new climate and/or sustainability related policies, such as net zero. Here, a similar array of governance instruments to those identified above are being proposed as a 'conveyor belt' that links them together to create a high-integrity governance ecosystem[31].

31 Hale, T. (2022) *The Net Zero governance conveyor belt.* Kleinman Centre for Energy Policy. https://kleinmanenergy.upenn.edu/wp-content/uploads/2022/12/KCEP-Net-Zero-Governance-Conveyor-Belt.pdf

2.3 The case for standards to support improved governance of innovation

The following types of standards are listed by BSI in its 'Introduction to Standards'[32]:

Prescriptive (normative) standards, comprising:

- Specifications: outline performance, design, and/or service requirements based on consensus;
- Methods of test: focus on the way products and materials are tested or the way they are specified; and
- Vocabularies: define terms used in a sector or technology.

32 Saunders, A. and Walton, S. (2022) *Introduction to standards.* BSI; Standards Foundation. https://www.bsigroup.com/globalassets/localfiles/en-gb/bsi_innovateu-kedge_standards-foundation-session_to-upload.pdf.

Non-prescriptive (informative) standards, comprising:

- Codes of Practice: provide guidance and recommended options from outline design to workmanship and safe practice;
- Guides: provide general guidance with recommendations and background information based on the current thinking and practices of subject experts; and
- Recommendations.

In addition, a **Publicly Available Specification (PAS)** is a sponsored standard developed relatively quickly (within 12 months) which does not require full consensus. A PAS is useful for fast moving technology sectors where it may be helpful to agree on a technical solution and publish it relatively quickly before going through the checks and balances needed for a full consensus standard (see Section 4.1).

A more recent type of standard made available by BSI which is potentially useful for the governance of innovative technologies is the ‘Flex’ standard, a sponsored standard intended to define good practice for a product, service or process. More specifically, “[A] PAS is best suited to areas where new concepts are becoming widely accepted and minimal change is expected [whilst] the BSI Flex is designed for emerging areas where there is a low level of certainty about ’what good looks like’, and good practice needs to evolve through a series of iterations.”[33]

Consensus-based standards have the potential to be more flexible and adaptive to the needs of innovative technologies than regulations with legislative back-up, hence their important role in the PAGIT Framework. Developing a BSI consensus standard, involving broad consultation and public review as part of the approval system, takes 12–18 months for a national standard and up to 3 years for an international one. Regulations generally take considerably longer to develop and, given a strong political or industry mandate, standards can be produced or adapted relatively rapidly.

Through their impact along a value chain on R&D, production, manufacturing, and market penetration, standards (often along with regulations) can contribute to the economic success of sectors and nations, and can promote innovation and shape markets[34] at micro- or macroeconomic levels. A recent BSI-funded report on the role of standards in driving transformative, disruptive innovation developed a conceptual governance model of the relationships between standards and regulations, reaffirming the innovation-enhancing capacity of standards[35].

33 BSI (undated). *Develop a fast-track standard: the fast, flexible solution (Collaborate, Innovate, Accelerate).* https://www.bsigroup.com/globalassets/documents/standards/guide-to-standards/creating_a_standard.pdf

34 Tassey, G., (2000). Standardization in technology-based markets. *Research Policy. (29)*, 587-602.

35 Blind, Knut (2023): Maximizing the impact of standards and regulation to drive transformative innovation: a new approach. Karlsruhe, Berlin: Fraunhofer Institute of Systems and Innovation Research, Report produced on behalf of Our 2050 World (commissioned by BSI) Executive summary, p5-7. (https://our2050.world/wp-content/uploads/2023/07/Maximizing-the-impact-of-standards-and-regulation-to-drive-transformative-innovation_Final-Version_V1_0.pdf)

Chapter three

Development of the PAGIT Framework

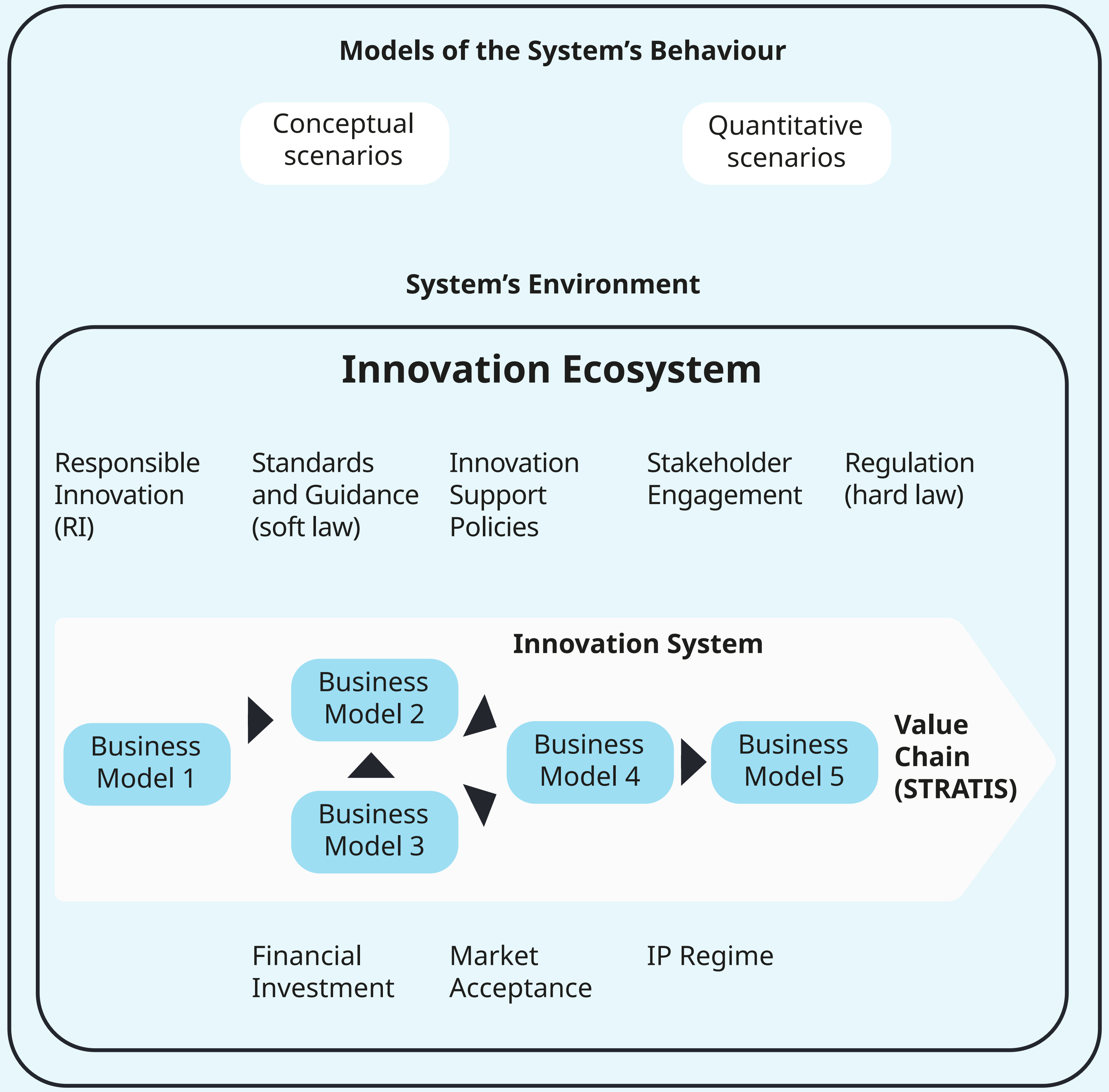
3.1 Foundational insights from the innovator's perspective

The PAGIT projects drew on the research described above on the interactions between innovative developments and the regulatory systems in place in the late 20th and early 21st centuries. We developed a systemic model of these interactions, Strategic Analysis of Advanced Technology **Innovation Systems** (STRATIS)[36] (see Figure 1), adopting the perspective of an innovator developing new products and services. This model focuses on the innovation system, the value chain for an innovation (the main arrow), and shows how, usually, a sequence of companies with different business models at different stages of product or service development (small arrows) need to work together to deliver the product or service to the market. The value chain is envisaged as being embedded within an **innovation ecosystem** encompassing the external factors that will influence how, and whether, innovative products and services are delivered to a market, and will determine, among other things, whether they are viable in the long run.

The innovation ecosystem in Figure 1 (**the system's environment**) includes some of the most important elements that can affect - positively or negatively - the ability of the innovation system to achieve its objectives. The elements shown above the value chain constitute the overall governance system: Regulation; Standards and Guidance; Responsible Innovation (including stakeholder engagement); and Innovation Support Policies.. These factors will determine the success or failure of the development of an innovation, either directly or through their influence on financial investment and market acceptance (elements below the value chain in the diagram). Conceptual or quantitative scenarios can be developed to support decision making on the development of innovative products and services and their future governance, focusing attention on the actions and interactions most likely to deliver desired outcomes.

36 Wield, D., Tait, J., Chataway, C., Mittra, J., and Mastroeni, M. (2017) Conceptualising and practising multiple knowledge interactions in the life sciences. *Technological Forecasting and Social Change, 116(3)*, 308-315 http://dx.doi.org/10.1016/j.techfore.2016.09.025.

Figure 1: Strategic Analysis of Advanced Technology Innovation Systems (STRATIS)



3.2 Applying the STRATIS approach: the innovator's perspective

This section summarises the tools needed to understand or explain the innovators' perspectives, to optimise governance-related decisions, ensuring safety, quality and efficacy, and avoiding unnecessary constraints on the development of innovative products and services.

Business models and value chains
In Figure 1, the value chain (and the contributing business models) are envisaged as the system designed to take innovative products from proof-of-concept stage to market availability, including all of the elements needed to deliver them, and an understanding of how they interact with each other.

Analysis of business models and value chains should take account of how the properties of an innovative product or service change over time, as it moves through Technology Readiness Levels and along a value chain. That progression, given accumulating knowledge of the relevant capabilities, benefits and hazards, will open up or close down future opportunities, changing the related governance questions and challenges raised from a governance point of view.

Technology readiness levels (TRLs)
Understanding and guiding the progress of an innovation across the various stages of its development, from basic research, proof of concept and technology development to final market availability is an important element of innovation governance. Doing so is a prerequisite to decision making on the most appropriate governance approach to be adopted and where and when to take action (see Section 3.3 for more detail). There will often be a series of business-to-business (B2B) transactions covering different aspects of product or service development before the final business-to-consumer (B2C) or end-user transaction, and different innovation challenges and regulatory requirements will be relevant at different stages. We adopted TRLs (see Figure 2) as one of the most widely used approaches to categorising the stages of technology development[37] focusing, for the purpose of this report, on TRLs 3-9.

37 EARTO (European Association of Research and Technology Organisations) (2014) *The TRL scale as a research and innovating policy tool, EARTO recommendations.* 30 April 2014. (https://www.earto.eu/wp-content/uploads/The_TRL_Scale_as_a_R_I_Policy_Tool_-_EARTO_Recommendations_-_Final.pdf)

Figure 2: Technology Readiness Levels 1 – 9

Invention	**1**	Basic principles observed	Translation of basic research to possible applications. Ideation, technology, foresight.
	2	Technology, concept formulated	
Concept validation	**3**	Final assessment, feasibility concept and technologies	Technological and applied product and process research. Preparation system integration. Early market assessment. Consortium building.
	4	Validation integrated prototype in lab environment	
			New technology
Prototyping and incubation	**5**	Testing prototype and user environment	Preparation of business. Prototyping facilities. Prototype system integration. Service development.
Pilot production and demonstration	**6**	Pre-production	Shared pilot production facilities. Contract research on product manufacturing. Business assessment.
	7	Low scale pilot production demonstrated	
Initial market introduction	**8**	Manufacturing fully tested validated and qualified	Contract research on product/process enhancements.
Market expansion	**9**	Production and product fully operationa	Contract research on incremental product/ process/service innovations.

Distinguishing disruptive and incremental innovation
An important factor to consider in using this approach as an aid to governance-related decision making is the extent to which the products and services concerned will be disruptive/transformative or incremental in their impact on company business models and sectoral value chains, and where in the value chain disruption is most likely to take place.

Disruptive/transformative and incremental innovation are defined here as follows: [38]

Incremental innovation (also described as path-dependent) 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, and will not lead to sectoral transformations. Most innovations are incremental including, for example, many of the innovations that have led to the improved energy efficiency of UK companies.

Disruptive innovation (also described as path-breaking) involves discontinuities in innovation pathways, requires new areas of research and development, and the 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 lead to stakeholder concerns from an early stage of development and there may be no obvious precedent to govern potential human and environmental safety issues. There may be no existing business model on which to build (as was the case when GM crops were first produced[39] or when Google first introduced its revolutionary search engine[40]), and there may also be a need to create new value chains, or new roles in existing value chains.

Transformative innovation is a concept that is equivalent to disruptive innovation, but tends to be used more in public- and policy-facing documents, while ‘disruptive innovation’ is more common in industry-facing contexts. For example, an adaptive standards-related decision for an incremental innovation at around TRL6, had significant impacts on the innovation capacity of a sector. The US Food and Drug Administration changed the guidelines for the conduct of clinical trials for new antimicrobial drugs and brought down the cost of their development by ~50%[41].
In some circumstances, adaptation of post-regulatory standards and guidelines, in the direction of strengthening them or adding new ones, may be needed to avoid negative outcomes from an innovative development.
For products of disruptive innovation, 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 governance system for the new technology.

38 Tait, J and Wield, D. (2019) Policy Support for Disruptive Innovation in the Life Sciences. *Technology Analysis and Strategic Management,* 33:3, 307-319. https://doi.org/10.1080/09537325.2019.1631449

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

40 Zuboff, S. (2019) The Age of Surveillance Capitalism: The Fight for a Human Future at the New Frontier of Power. New York: Public Affairs.

41 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.

Linking business models, value chains, TRLs and disruptive/incremental innovation

The research that involved the creative juxtaposition of these innovation-related concepts formed the foundation for the work on development of the PAGIT Framework. Deciding whether an innovation is disruptive or incremental is not straightforward and the concepts are in practice more fluid than implied in our definitions. The extent of disruption depends on the nature of the affected value chain, the location within that value chain of the expected disruption and whether the disruption affects the manufacturing process for the product or the product itself. So, an innovation initially classed as incremental may be found on closer inspection to have elements of disruption for the business models of some incumbent companies.

Two examples can illustrate these points:

1. **The industrial biotechnology value chain** for high-value chemical intermediates involves: companies (usually SMEs) developing, testing and upscaling the microbial production of the chemical; large scale production of the chemical using the new bio-manufacturing method; companies formulating the chemical to manufacture and distribute detergents, perfumes, food and feed additives, etc.; and the final consumer-facing outlets for the product. In this case, disruption of business models mainly affects the large petrochemical companies that were previously manufacturing the chemicals, potentially to be replaced by new companies with expertise in large scale fermentation[42]. Thus, an innovative technology can disrupt the business models of one of the participating sectors in a value chain with relatively little impact on companies in the rest of the value chain, e.g. those using the chemical intermediate to manufacture the end products sold to consumer markets. There may be a need for new standards in such cases to ensure that the chemical intermediates developed using a fermentation process are fully equivalent to those they are replacing, but no need for changes at other points in the value chain.

2. 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, the chosen basis for regulation of GM products, where they impacted across all TRLs on R&D, product manufacture, distribution and markets[43]. GM related innovations would have been least 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. The lesson from this research was that, for a disruptive innovation, regulators should consider first the governance system in place for the sector for which such products would be least disruptive, in this case the seeds sector where governance would have focused on plant breeders' rights and national listing of new crops[44].

42 Tait, J and Wield, D. (2019) Policy Support for Disruptive Innovation in the Life Sciences. *Technology Analysis and Strategic Management,* 33:3, 307-319. https://doi.org/10.1080/09537325.2019.1631449

43 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.

44 https://www.bspb.co.uk/plant-breeding/regulation-testing-and-protecting-varieties/

Both cases (explored further in Sections 5.2 and 5.3) are relevant to today's focus on climate change, net zero,[45] and biodiversity protection (for example through the UN Sustainable Development Goals (SDGs))[46]. Industrial biotechnology can replace fossil fuels with bio-based ingredients, in some cases using waste products from other industry sectors and contributing to a circular bio-economy[47]. The use of GM and new genetic technologies in agriculture can contribute to diminishing both climate change (net zero) and biodiversity-related impacts of crop production[48].

45 UK Government Department for Energy Security and Net Zero and Department for Business, Energy and Industrial Strategy (2021) Net Zero Strategy: Build back greener. https://www.gov.uk/government/publications/net-zero-strategy
46 UN Department of Economic and Social Affairs. https://sdgs.un.org/#goal_section
47 Tait, J., Raybould, A., Flight, M.H. and McGoohan, A. (2023). Circular and Networked Bioeconomies for Net-Zero Food Production: There is Nothing Magic about Circles. *Circ.Econ.Sust.* (2023). https://doi.org/10.1007/s43615-022-00247-w
48 Brookes G, Barfoot P. Environmental impacts of genetically modified (GM) crop use 1996-2016: Impacts on pesticide use and carbon emissions. GM Crops Food. 2018;9(3):109-139. doi: 10.1080/21645698.2018.1476792. PMID: 29883251; PMCID: PMC6277064.

3.3 The regulator's or policy maker's perspective on the governance of innovative products and services: development of the PAGIT Framework.

The benefits of innovative technologies, including the economic, climate change and biodiversity-related benefits, will only be achieved if relevant products and services can be brought to market through a timely, economically viable and internationally competitive governance system. The BSI PAGIT projects aimed to demonstrate how governance approaches and regulatory systems could be adapted, where necessary, to unlock the potential of emerging innovative technologies while maintaining expected standards of safety, quality, and efficacy.

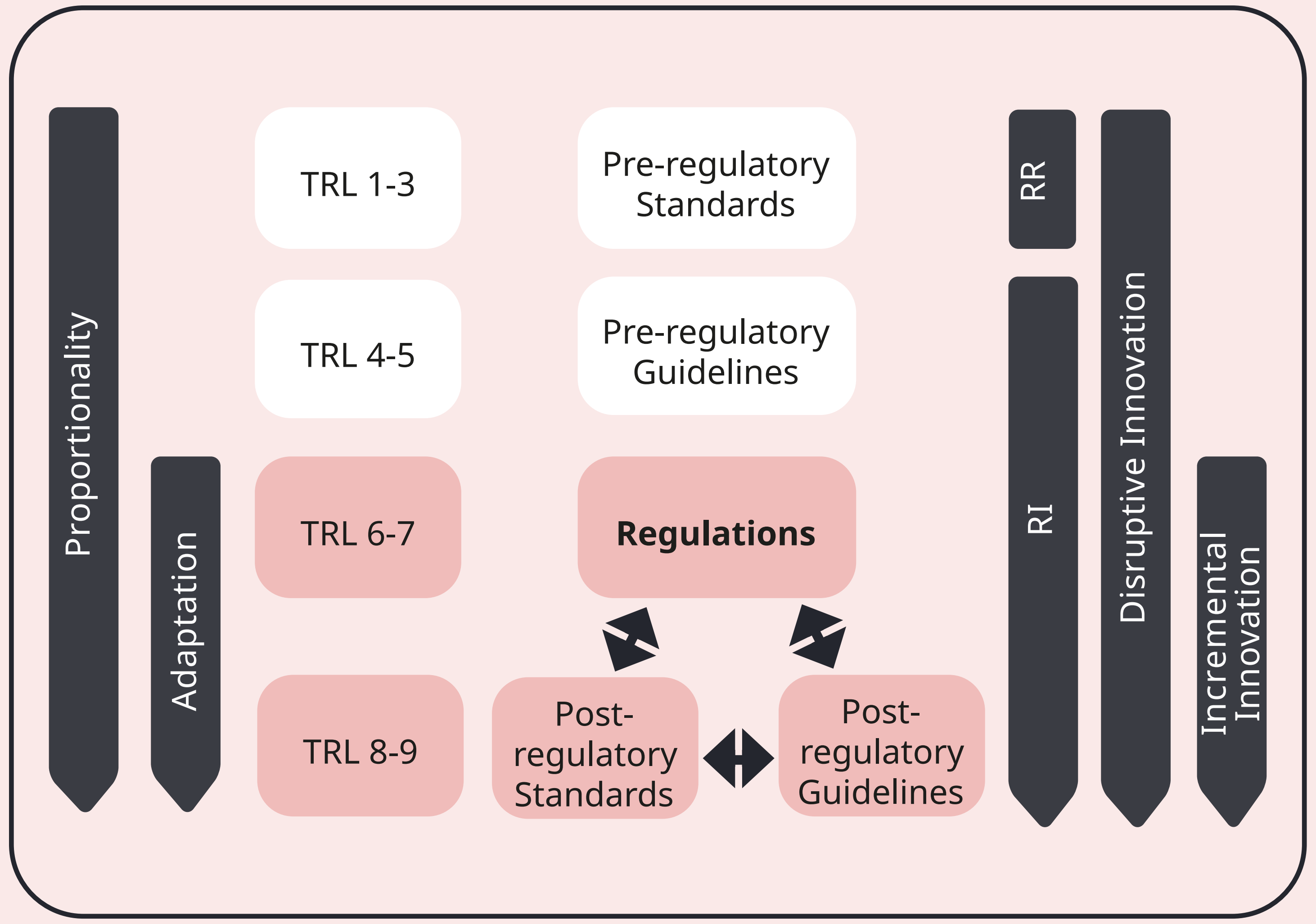
Combining the insights from innovators' perspectives (see Sections 3.1 and 3.2) within a systemic approach to the governance of innovative technologies and recognising the creative potential of distinguishing between pre-regulatory and post-regulatory standards were novel contributions, enabling practical solutions to the challenges that had been identified for the governance of innovative technologies. The PAGIT Framework (see Figure 3) adopts a regulators'/policy makers' perspective on the governance of innovation[49], leading them to consider how the governance requirements of an innovative development change as they are translated along a value chain from TRLs 3-4 (concept validation) to TRLs 8-9 (market introduction and expansion) (see Figure 2). As noted below, a disruptive innovation should also be given careful attention at TRLs 1-3, while avoiding any irrevocable regulatory decisions.

At TRLs 5-6 regulators and policy decision-makers should consider the following factors:

- whether the properties of a product or service justify the introduction of a legally based regulatory system;
- if so, which current regulatory system 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 a particular product or service, or whether a new regulatory system would need to be developed.

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

Figure 3: PAGIT Framework



Applying the PAGIT Framework to the governance of innovative technologies

The role of the TRL scale within the PAGIT Framework is partly to help decision makers to avoid resorting prematurely to legally-based regulation before TRL 6 which could then be difficult to adapt to changing understanding of an innovation's properties at later TRLs. Standards and guidelines are usually better choices to govern the early development stages of an innovative product or service at TRLs 4 – 5 while further investigations are conducted to understand the evolving properties of the product or service and its governance requirements. This enables the choice of governance approach at TRL 6 to be based on, and more proportionate to, the properties of the innovative product or service, avoiding the need to adapt it later (which can be excessively time-consuming and bureaucratic). The TRL scale is thus used here as a guide to the timing and sequencing of governance-related decisions in the process of transitioning an innovative technology from the proof-of-concept stage to a commercial product or service.

Figure 3 shows how incremental innovation, with an uncontentious and previously well-established governance pathway usually only requires governance-related attention at TRL 6 and beyond whereas, for disruptive innovation, governance-related issues can be relevant at any point from TRL 1 onwards.

The following points are relevant to the application of the Framework across the TRL scale:

1. **TRL 1-3 (Pre-Regulatory Analysis)**. For a **disruptive innovation** both innovators and regulators should begin to think about its future governance based on its expected future properties, even though these will likely change by TRL 4. Early research choices about product and service development can have a major, sometimes unexpected, impact on its governance and hence its chances of future market viability.
2. **TRL 4-5 (Pre-Regulatory Standards and Guidelines)**. For a **disruptive innovation**, focus on 'aspirational' or consensus standards and guidelines, particularly to ensure safety to human health and the environment while conducting translational research (research to transform the results of basic scientific research into new products and services that are economically viable and satisfy human and/or environmental needs). Only if necessary, these governance instruments could then form the basis of a future legally-based regulatory system, but decision makers should be open to the possibility that standards and guidelines alone may be sufficient to ensure safety, quality, and efficacy.

3. **TRL 6-7 (Regulatory Decision Point)**. TRL 6 is a particularly important stage for the governance of a **disruptive innovation**, when a decision is made on which existing governance approach (hard law or soft law based) is most appropriate to the properties of the innovative technology or, if necessary, to consider devising a new governance approach. Where legally-binding regulations are adopted they should, as much as possible, be couched in general terms relating to their desired outcomes and be supported by post-regulatory standards and guidelines that can be more easily adapted to any future changes in understanding of the properties of the innovation. For an incremental innovation at this stage, there will usually be a clear regulatory precedent but, where a new product or service is unnecessarily challenged by any aspects of the prevailing governance system, innovators, policy makers, and regulators should collaborate to find a solution.
4. **TRL 8-9 (Post-Regulatory Standards and Guidelines**). For **both disruptive and incremental innovation**, as appropriate, regulators and policy makers should devise standards and guidance, either to support compliance with regulations by those engaged in developing a new product or service, or to form the basis of future governance without the need to resort to legally-based regulation.

3.4 Governing innovative products and services: whether to take a product or process-based approach

As noted in Section 3.2, an innovative technology which is disruptive will face questions about how related products and services should be governed at early stages of their development.

Beginning in the 1980s with GM technologies and more recently with AI and Quantum, at least some of the discussion amongst regulators has centred around regulating the technology itself, implying that the products would all be covered by a common regulatory approach, one based on the properties of the development process (described as 'process based'), rather than the specific properties, risks, and benefits of the individual products (described as 'product based')[50].
To illustrate, the process-based approach became prominent when the EU applied the same regulatory approach to all GM products regardless of their nature, purpose, or the extent of their risks and benefits. On the other hand, the US adopted a product-based approach (to these products), where approval is dependent on the properties, risks and benefits of the final product.

50 Gould, F. *et al.,* (2022) Toward product-based regulation of crops. *Science*, 377, 1051-1053. DOI:10,1126/science.abo3034

The EU's process-based governance systems have been disproportionately costly and time-consuming for products derived from genetic technologies and only large multinational companies have been able to take products and services all the way to market, restricting the scope and scale of innovation across the board. A process-based governance system is also much more difficult to adapt to changes in product risk profiles resulting from innovative developments like engineering biology and gene editing[51]. The fact that GM products have been successfully developed in the US and not in the EU has been attributed to this dichotomy in approaches to their regulation. However, recently it has become more acceptable to propose that it is *not* advisable to regulate an innovative technology on the basis of the production process but, instead, to do so on the basis of the properties of the product or service itself (see Section 5.2).

That said, a product-based regulatory system faces a different set of challenges. It requires a choice to be made as to which is the most appropriate regulatory precedent for a disruptively innovative product (Section 1.1); further, in some cases, there may be no obvious precedent and poor decisions here are likely to inhibit innovation (where the application of the regulatory system for drugs to GM fish is an example).

51 RHC (2022) *Regulatory Horizons Council Report on Genetic Technologies*. https://www.gov.uk/government/publications/regulatory-horizons-council-report-on-genetic-technologies

A decision to choose the production process as the basis for regulatory decisions is most likely to be made in very early TRLs (around TRL3) and it will have downstream impacts on all potential products arising from the new technology, in that they may never be developed and therefore never reach regulatory consideration as novel products. On the other hand, product-based choices should be considered around TRL6, when there is more evidence about the properties of the product, including in terms of its risks and benefits (see Section 3.3). A poor choice at TRL6 may therefore knock out future innovation in a particular sector, although the effect will not be as wide-ranging as a poor process-based choice (see also Section 6.1).

3.5 Summarising the benefits of a PAGIT-based approach

Bringing together the perspectives of innovators and regulators, as described here leads to a governance system with the following attributes:

- It conforms with the regulatory principles - proportionality, adaptation, balance, and responsible innovation;
- It is technology neutral and can be applied to different degrees and types of innovation, across different industry sectors with widely differing histories and experiences of regulation;
- It could unlock greater commercial value from emerging technologies while also addressing regulatory and public concerns about safety, quality, and efficacy of products and services;
- It focuses on the specific properties of the innovative products and services themselves, not on the generic technology used to develop them;
- It incorporates, as appropriate, the full range of governance instruments, including legally-based regulations, along with (i) *pre-regulatory standards* at TRLs 4 – 6 where they can be used creatively to support safe and effective development of an innovative product or service before making a decision on whether legally-based regulation will be required; and (ii) *post-regulatory standards,* using them to support innovators' compliance with the requirements of a legally-based regulatory system or as an alternative to regulation;
- It links governance-related actions to the stage of development of the relevant product or service using the TRL scale;
- It considers the extent to which a product or service is incremental or disruptive for incumbent company business models, for which companies or sectors it will be most disruptive, and the location of the disruption within a value chain, using this understanding to guide decisions on the nature and targeting of regulatory instruments; and
- It supports alignment across the perspectives of stakeholders in an innovative sector, including industry, regulatory bodies, consumer, and citizen representatives through the uptake by companies of a responsible innovation (RI) approach (see Section 4.1).

Chapter four

The PAGIT Framework's influence

on the UK governance landscape for innovative technologies

The PAGIT reports played an important role in the recent evolution of UK governance systems through the White Paper report on Regulation for the Fourth Industrial Revolution[52] (see Section 4.2). Better governance decisions about innovative technologies will contribute to the UK government's aspirations to lead internationally in developing pro-innovation regulation[53] and in delivering on its climate change and biodiversity-related policies.

The value of the PAGIT Framework lies in its ability to manage systemic interactions across industry sectors at different TRLs, with different governance-related requirements, and involving different stakeholder constituencies. It provides guidance on which elements are relevant to particular governance decisions and how PAGIT-related insights could guide the governance of products as they pass along a value chain. It is intended to be applied in a flexible way, focusing on the elements that are most relevant to a particular decision. Its adoption opens up the potential for a dramatic improvement in the efficiency of operation of governance systems and the speed and cost effectiveness of delivery of regulatory decisions. The intention is that this should lead to an increase in the number of UK research projects that deliver successful innovations to the marketplace, with a corresponding increase in the value for money generated from public and private investment in scientific research.

52 HM Government (2019) *Regulation for the Fourth Industrial Revolution.* White Paper, CP 111. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/807805/regulation-fourth-industrial-strategy-white-paper-print.pdf.

53 HM Government (2023) Pro-Innovation Regulation of Technologies Review: Life Sciences. Authored by Dame Angela McLean, May 2023. https://assets.publishing.service.gov.uk/media/64706d21c38c55000c342bd5/Life_sciences_report_-_Pro-innovation_Regulation_of_Technologies.pdf

The PAGIT Framework implies the following decision criteria for regulators, policy makers, and standards bodies:

1. Deciding whether the governance system for an innovation should be based on the properties, benefits and risks of the end product (**product-based**) or on the basis of the technology used to produce it (**process-based**) (see Section 3.3). The recommendation is that product-based governance approaches are generally to be preferred.
2. For **incremental innovation**, there will generally be a clear, uncontested regulatory choice. However, if the expected regulatory choices are unnecessarily inhibiting their further development, this can often be dealt with through revision of post-regulatory standards and guidelines at TRLs 7-9.
3. For a **disruptive innovation**, regulators and standards bodies should build on a staged approach, beginning with the development of pre-regulatory standards and guidelines at TRLs 3-5 to provide a better-informed basis for decisions on the need for a legally based regulatory system and the future role of standards and guidance at TRL 6.

iv. In deciding on a future governance system for a potentially disruptive innovation, consider first the system in operation for the sector for which the technology will be least disruptive (see Section 3.2)[54].

v. 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. Where there is disruption to the business models of companies operating at earlier stages of the value chain (such as a manufacturing system or development of novel feedstock), this may be less likely to lead to citizen concerns[55].

vi. Applying the revised PAGIT Framework to an innovative technology across TRLs 3-9 can also be required for an incremental innovation where the expected governance system is disproportionate and/or is influenced by stakeholders with ideologically based opposition to a technology, e.g. the EU governance systems for genetic technologies and vaccine-related developments.

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

55 Monica Hoyos Flight, Joyce Tait, Theo Chronopoulos, Monica Betancor, Pauline Wischhusen, Emily Burton, Helen Masey O'Neill Kim van der Heul7, John Hays and Peter Rowe (2024, in press). Analysing Responsible Innovation along a value chain – a single-cell protein case study. *Engineering Biology.*

This advice is relevant to a broad range of innovative technologies and sectors where the UK sees itself as leading in the field, including autonomous and low-emission vehicles, FinTech, robotics, battery technologies, quantum technologies, industrial biotechnology, and life sciences (such as, pharmaceuticals, cell therapies, gene editing, synthetic biology, stratified medicine, agricultural and food technologies). It is also relevant to the delivery of successful governance options to meet current global challenges related to net zero, climate change mitigation and adaptation, and biodiversity loss, given the important role of innovative products and services in these areas. More proactive involvement of pre-regulatory standards in the early development of governance systems, along with more agile and adaptive adoption of post-regulatory standards (see Figure 3), could play a major role in supporting future delivery of the UK's pro-innovation governance approach.

Two recommendations from the PAGIT reports have been particularly influential on subsequent developments in the governance of innovative technologies:

1. Through BSI, development of a standard on Responsible Innovation (RI) (see Section 4.1); and
2. Exploring opportunities to use the PAGIT Framework to optimise the UK's governance systems for innovative technologies (see Section 4.2).

4.1 The Development of a Guide to Responsible Innovation: PAS 440

Based on recommendations in the PAGIT Reports, Innovate UK funded BSI to develop a Publicly Available Specification (PAS, see Section 2.3) on Responsible Innovation (RI)[56], to provide the support needed by companies across all innovative sectors, first to assure themselves that they are behaving responsibly and, second but equally important, to demonstrate their responsible behaviour to stakeholders. The PAS is designed to be simple and feasible for a company, even a small company, to implement within the constraints of a commercial environment, setting out clearly what can be expected from smaller companies with limited resources.

The need for an RI standard arose from the gap in guidance for companies developing innovative products and/or services on how to include *formal* consideration of their benefits and hazards as part of responsible innovation, in addition to the company-specific social responsibility aspects. Development of PAS 440 is also relevant to policy pressures for pro-innovation regulatory reform, given the need for societal acceptance of such strategies. Compliance with the RI Guide would provide public reassurance that such adaptation is not leading to companies lowering overall governance standards.

56 BSI (2020) *Responsible Innovation Guide - PAS 440.* https://www.bsigroup.com/en-GB/insights-and-media/insights/brochures/pas-440-responsible-innovation-guide/

The most important elements of PAS 440, setting it apart from most other approaches to RI, are:

1. It distinguishes between (a) routine, company-wide aspects of responsibility, expected to be addressed within an organisation's standard operating procedures and applicable to all companies, as per 'ISO 26000 – Social responsibility'[57]; and (b) innovation-specific aspects, applicable to companies actively involved in innovation, requiring regular reappraisal throughout the development of a product or service, and most likely to be necessary for disruptive innovations (although it will also be needed where incremental innovations become the subject of negative public or stakeholder attention);
2. It distinguishes between incremental and disruptive innovation in that, for incremental innovation, RI criteria will generally be satisfied by compliance with a company-level social responsibility standard, whereas disruptive innovation will also require attention to technology-specific responsible innovation;It supports companies by providing a framework to demonstrate the balance between the potential benefits and harms of an innovative development and, if necessary, to take action to maximise the benefits and/or minimise the harms;

- It recognises that what constitutes responsible behaviour will vary as an innovation progresses along a value chain from proof-of-concept stage (TRLs 4-5) to market availability (TRL 9);
- It includes guidance on engagement with stakeholders, incorporating a more balanced consideration of the potentially diverging interests and values of different stakeholders;
- It specifically links RI to meeting the requirements of net zero government policies and the UN's Sustainable Development Goals;
- The RI Framework within PAS 440 (see Table 1) is intended to be easily understood by companies of any size and their stakeholders. It builds on procedures that are already familiar to most companies, such as compliance with a social responsibility standard and using a risk assessment matrix as part of conventional project management;

3. It explicitly incorporates the need to be aware of, and to comply with, other existing regulations and standards; and
4. Stakeholder engagement is an important part of RI, and contributes to the completion and regular updating of the Framework, particularly for disruptive innovations and any others that are potentially contentious
5. Within stakeholder engagement, *all* stakeholders need to engage responsibly, not just the companies involved (see Table 2)[58,59].

PAS 440's iterative procedure requires a company to revisit its RI monitoring at intervals appropriate to the speed of development of the innovation and takes account of any substantive changes in its properties or in plans for future market targeting.

57 https://www.iso.org/iso-26000-social-responsibility.html

58 Lynas, M. (2018) Seeds of science: why we got it so wrong on GMOs. Bloomsbury Publishing.

59 Lyall, C. and Tait, J. (2019) Beyond the Limits to Governance: new rules of engagement for the tentative governance of the life sciences. *Research Policy,* 88(5), 1128-1137. *https://doi.org/10.1016/j.respol.2019.01.009*

Table 1: Responsible Innovation Framework Template (PAS 440:2020, Section 7.2).

RIF Assessment Heading:
Reference number/iteration number:

Innovation vision, description, targets and success measures:

Named responsible person or role (contact details):

Stage of development (early, middle, late):

Date of completion of this version:

Dates of completion of all previous versions of the RIF for this development:

1. ID #	2. Elements of RI - identify positive and negative outcomes of the innovation(s) (see 7.3)	3. Record the reasons for inclusion of the element in the baseline assessment (see 7.3) and note any changes to elements since the previous iteration of the RIF (see 8.2)	4. Identify (see 7.4) and engage with (see 8.3) stakeholders	5. Take action (see 7.5 and 8.4)
1.x	Societal elements (benefits)			
2.x	Societal elements (risks)			
3.x	Environmental elements (benefits)			
4.x	Environmental elements (benefits)			
5.x	Health-related elements (benefits)			
6.x	Health-related elements (risks)			
7.x	Value chain elements (RI behaviour by other significant actors)			
8.x	Regulatory elements			

Table 2: Responsible Engagement Guidelines (PAS 440: 2020, Section 8.3.2)

a.	Ensure equitable treatment across all stakeholders: i) discussions should be open and accommodate the full range of relevant opinions; ii) agendas should be flexible and allow stakeholder input; and iii) no single perspective should dominate other opinions or dictate the terms of engagement.
b.	As part of a staged approach to RI, specific aspects of the engagement should be tailored to the relevant development stage to consider: i) who should be involved; ii) which topics are relevant to be addressed; and iii) whether and how the outcomes should be implemented.
c.	Engagement should be carefully timed: i) too early (upstream) and its value will be undermined by uncertainty about the nature of future developments; ii) too late and it may be too expensive to change the design of a particular commercial offering, or stakeholder opinions and political positions may have become entrenched so that accommodation or consensus will be more difficult to achieve.
d.	Accept that consensus may not be attainable and manage expectations accordingly.
e.	The dialogue should inform stakeholders about the nature of innovation processes - how scientific discoveries are translated to useful products, processes and services and how they will be regulated.
f.	Ensure a balanced consideration of benefits and risks associated with the innovation, and where its impacts accrue.
g.	Do not allow the values and/or interests of one stakeholder group to restrict the freedom of choice of others
h.	Include standards for the quality and breadth of evidence that is considered as a basis for discussion and decision making.
i.	Where there are conflicting values and interests, be equitably sceptical about the impartiality of evidence presented in support of any particular case.
j.	Where there is conflicting evidence, consider carefully the expertise of those promoting the evidence, including both scientific and experiential expertise, and weight it accordingly.

Section 5.5 presents a case study based on the use of the RI Framework within PAS 440.

4.2 The PAGIT Report's role in the development of the UK's pro-innovation governance initiatives

The PAGIT Report contributed to a series of UK Government initiatives on pro-innovation regulation initiated through the Council for Science and Technology (CST) since 2018. The focus has been on the governance frameworks that affect how businesses may develop, test, and sell products and services built on new technologies, striking an appropriate balance between offering stability and certainty for investment decisions, the need to adapt to changing circumstances, and helping to ensure that desirable innovation is not stifled.

In 2017-18, based on the PAGIT Report, a CST initiative was set up, preparing a letter to Prime Minister Theresa May[60] with recommendations on:

1. Developing a horizon-scanning function located in the Better Regulation Executive (BRE);
2. Considering guidance, codes, and standards alongside formal regulation as part of a more flexible and responsible approach to governing innovation;
3. Providing a 'one-stop-shop' for UK governance-related enquiries; and
4. Evaluating governance of innovation including setting up 'test beds' to try out emerging innovations safely.

60 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/750786/cst-reforming-the-governance-of-technological-innovation.pdf

A rapid response to this letter was received[61], confirming the government's intention to implement these recommendations. The resulting White Paper on *Regulation for the Fourth Industrial Revolution*[62] committed the UK Government to the following actions:

1. To establish a Regulatory Horizons Council to conduct horizon-scanning work and recommend priorities for regulatory reform to the Ministerial Working Group on Future Regulation;
2. To improve the use of regulatory guidance, codes of practice and industry standards, including piloting an innovation test bed to consider the impact of legislation on innovation alongside working with bodies such as the BSI to review the use of standards;
3. To consult on a digital 'Regulation Navigator' for businesses to understand UK regulation, funding for specialist regulatory advisor services, and encourage co-ordination between regulators; and
4. To support experimentation through considering an extension of the £10M Regulators' Pioneer Fund, establishing a Regulators' Innovation Network.

61 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/750370/beis-reforming-the-governance-of-technological-innovation.pdf

62 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/807805/regulation-fourth-industrial-strategy-white-paper-print.pdf

The Regulatory Horizons Council (RHC) was established in 2019 as an independent expert committee that identifies the implications of technological innovation with high potential benefit for the UK economy and society, and provides government with impartial, expert advice on the regulatory reform required to support its rapid and safe introduction. Table 3 details its reports to date whilst the case studies described in Sections 5.1 and 5.2 are based on the reports on Genetic Technologies and Quantum Technology Applications.

Table 3: RHC Reports (to date) 63.

Generalist reports	Technology specific reports
The Role of Regulation in Supporting Scaling up (2024)	Regulating Quantum Technology Applications (2024)
Closing the Gap: Getting from Principles to Practice for Innovation-friendly Regulation (2022)	Regulation of Robotics and Autonomous Systems in Agriculture and Horticulture (2023)
	The Regulation of Hydrogen Fuel Propulsion in Maritime Vessels (2023)
	The Regulation of Artificial Intelligence (AI) as a Medical Device (2023)
	Neurotechnology Regulation (2022)
	Drones Regulation (2021)
	Genetic Technologies (2021, updated in 2022)
	Medical Devices Regulation (2021)
	Fusion Energy Regulation (2021)

Another relevant initiative was the publication in 2023 of a series of papers from the Government Chief Scientific Adviser, as part of the government's Pro-innovation Regulation of Technologies Review[64], including a sector specific report on Life Sciences[65], which built on the PAGIT report's recommendations.

63 https://www.gov.uk/government/groups/regulatory-horizons-council-rhc#reports

64 https://assets.publishing.service.gov.uk/media/655cd10a-d03a8d001207fdfd/_8243__GCSA_Pro_Innovation_cross_cutting_Report_PDF.pdf

65 HM Government (2023) Pro-Innovation Regulation of Technologies Review: Life Sciences. Authored by Dame Angela McLean, May 2023. https://assets.publishing.service.gov.uk/media/64706d21c38c55000c342bd5/Life_sciences_report_-_Pro-innovation_Regulation_of_Technologies.pdf

Chapter five

Use of the PAGIT Framework:

Case Studies

5. Use of the PAGIT Framework: Case Studies

In the examples of its application described in this section, the elements of the PAGIT Framework that have been most valuable include:

- emphasis on regulation of products and services rather than the process from which they were derived;
- understanding the evolution of business models and value chains across the range of TRLs;
- distinction between disruptive and incremental innovation in governance systems; and
- the relative roles of standards, guidance and legally-based regulation, including standards for behavioural practices such as responsible innovation.

The advice to consider 'regulating the product, rather than the process' did not feature as prominently in development of the PAGIT Framework as its other elements. However, its importance became clearer in application, given the PAGIT focus on products and services and their developmental life cycle, with changing business models, different roles in a value chain, gradually increasing understanding of their capabilities and challenges, and different markets (B2B and B2C) (see Sections 5.3 and 5.4).

The framework was applied in a flexible, non-prescriptive way, contributing to the case studies where its elements were relevant to particular governance decisions for disruptive and incremental innovation at specific points along a value chain.

5.1 Regulatory Horizons Council's (RHC) Report on Genetic Technologies [66]

Background
The RHC was commissioned by the UK government to examine how genetic technologies would benefit from governance-related reform, in particular crop and animal products of genetic technologies (as used in the agri-food and environmental sectors). Genetically modified plants and animals have been subject in Europe to a governance regime that has inhibited commercial developments based on these technologies since it was introduced in the 1980s. This area warranted urgent attention because of its ability to contribute to the transformation of agriculture and food-related sectors of the economy while also meeting net zero and biodiversity policy targets, a potential underpinned by the UK's expertise and track record in conducting scientific research in this area.

66 RHC (2022) Report on Genetic Technologies. https://assets.publishing.service.gov.uk/media/62c809d5d3bf7f3004d17f6f/regulatory_horizons_council_report_on_genetic_technologies_july_2022.pdf
RHC (2022) Reforming the Governance of Genetic Technologies. Policy Brief. https://assets.publishing.service.gov.uk/media/62bef4068fa8f578be2f7b71/regulatory_horizons_council_policy_brief_on_genetic_technologies.pdf
RHC (2021) Annex A. Optimising the governance of genetic technologies. Issues paper. https://assets.publishing.service.gov.uk/media/612df69fd3bf7f0387e8aa07/rhc-genetic-technologies-annex-a.pdf

The PAGIT Framework contributed to the report's recommendations in relation to:

Product-, not process-based, governance
The RHC report recommended the adoption of a more proportionate and adaptive, product-based regulatory system for genetic technologies in the UK (as distinct from the EU approach which focuses on the process of genetic modification itself and includes all products, regardless of their properties, within a common governance regime) (see Figure 4); specifically:

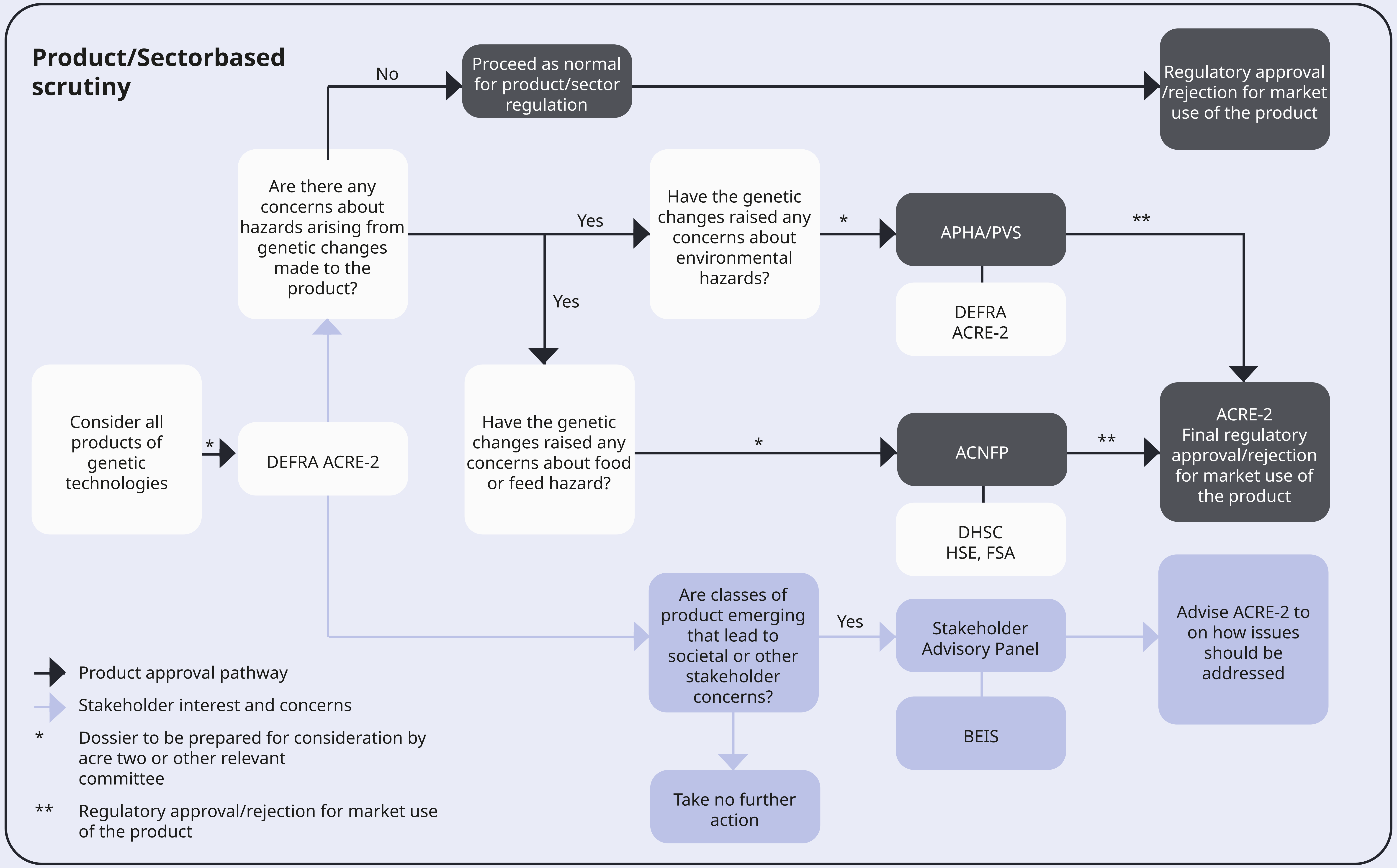
Recommendation 2 of the report advised that governance-related scrutiny should focus on the product to be placed on the market and the balance between its risks and benefits (rather than the process used to develop it).

Recommendation 4 advised that data requirements should be proportionate to the nature and scale of the product's potential risks[67].

These views have been supported by a more recent Royal Society report[68]. Further, as proposed in the PAGIT Report, countries that make proportionate, adaptive, and product-based regulatory decisions will see the greatest economic, societal, and environmental benefits from genetic technologies, particularly those related to meeting net zero and biodiversity related challenges.

67 RHC (2022) *Reforming the governance of genetic technologies: Policy Brief by the Regulatory Horizons Council*. (https://assets.publishing.service.gov.uk/media/62bef4068fa8f578be2f7b71/regulatory_horizons_council_policy_brief_on_genetic_technologies.pdf).
68 The Royal Society (2023) *Enabling genetic technologies for food security.* Policy briefing. ISBN: 978-1-78252-682-7. (https://royalsociety.org/-/media/policy/projects/gene-tech/genetically-modified-organisms-regulation-policy-briefing.pdf).

Figure 4: Proposed regulatory pathway for products of genetic technologies used in agriculture, food production and other uncontained conditions§ (RHC's Report on Genetic Technologies, Section 6.2)



§ ACNFP-Advisory Committee on Novel Foods and Processes; ACRE-Advisory Committee on Releases to the Environment; APHA-Animal and Plant Health Agency; BEIS-Department for Business, Energy and Industrial Strategy; DEFRA-Department for Environment, Food and Rural Affairs; DHSC-Department for Health and Social Care; FSA-Food Standards Agency; HSE-Health and Safety Executive; PVS-Plant Variety Rights and Seeds Office.

Role for standards and guidelines in future governance systems
The PAGIT Framework focuses strongly on the role of standards and guidelines in facilitating regulatory adaptation and in the design of future regulatory systems for both disruptive and incremental innovative technologies (see Section 3.4). This inevitably leads to considerations of the stage of development of an innovative product or service and the extent to which it is seen as disruptive (or incremental). Recommendation 5 of the RHC's report proposes that standards and guidelines (instead of 'hard law' legislation) should facilitate regulatory adaptation where possible, including labelling to indicate both a product's origins and the potential societal and environmental benefits of its use, as appropriate.

Role of Responsible Innovation (RI)
The innovation principle is not unconditional, and entrepreneurs are increasingly expected to innovate in a responsible manner. Genetic modification, involving cross-species genetic transfer, was the first of the genetic technologies to lead to commercial products on the market (mainly in the form of modified crops). The need for dialogue related to public opposition to the use of GM products led to the development of the Responsible Research (RR) agenda[69], and the RHC report - proposing how RI could operate in this context - included an amended version of the responsible engagement guidelines from PAS 440 (see Table 2), for use where opinions are likely to be polarised (Section 4.2 of the RHC report).

Recommendation 7 of the report also proposed the setting up of a Stakeholder Advisory Panel by UK regulators, including public representatives and all other relevant stakeholders, to contribute to the adaptation and operation of the UK governance regime and to the outcomes of its decisions. Its role could enable regulators to experiment and to learn from the experience of others and also build on BSI's experience of its Consumer & Public Interest Network[70] and the Sustainability Standards Network[71].

69 Tait, J. (2017) From Responsible Research (RR) to Responsible Innovation (RI): challenges in implementation. *Engineering Biology,* 1(1), 7-11. DOI: 10.1049/enb.2017.0010
70 Consumer & Public Interest Network (CPIN) https://www.bsigroup.com/globalassets/localfiles/tr-tr/tuketici-yayinlari/bsi-consumer-brochure-cpin-uk-en.pdf
71 Sustainability Standards Network https://www.bsigroup.com/globalassets/documents/about-bsi/nsb/sustainability-standard-network/s20158_bsi_sustainability-standards-network-4pp-brochure-web.pdf

Conclusions
This report was partly informed by the experience of developing the PAGIT Framework and this played an important role in highlighting some of the contradictions inherent in putting the recommended 'product-based' approach into practice (see Section 3.3), prompting further consideration of the issue of regulatory capture within the Framework.
The recommendations and the proposed governance pathway (see Figure 4) demonstrated how application of specific elements of the PAGIT Framework could deliver a more effectively targeted, cost-effective governance system for these technologies in the UK on a more rapid timescale, and in keeping with international developments in this area.

5.2 Regulatory Horizon Council's (RHC) Report on Regulating Quantum Technology Applications[72]

As with the previous case study, this section describes an application of the PAGIT Framework to the future governance of another disruptively innovative set of technologies – quantum technologies. This is a more challenging application of the PAGIT Framework compared to the first case study, given that it is an area that is technically very different from the life science sectors within which the Framework was developed.

Background

The RHC was commissioned by the Office for Quantum through the UK's 2023 National Quantum Strategy, "to undertake a regulatory review of Quantum Technology applications"[73]. The question to be answered was, "What regulatory and governance approaches and measures are needed now, and in the near future, to facilitate the rapid and safe introduction of innovative quantum technology applications?" The UK is well-placed to benefit from innovative products and services arising from quantum technology developments, with the potential to increase greatly computing power and precision in measurement, and to transform numerous sectors from health care to national security.

72 RHC (2024) *Regulating Quantum Technology Applications.* https://assets.publishing.service.gov.uk/media/65ddc83bcf7eb10015f57f9f/RHC_regulation_of_quantum_technology_applications.pdf

73 Department for Science, Innovation and Technology (2023). *National quantum strategy.* (https://www.gov.uk/government/publications/national-quantum-strategy)

Given the timescale featured in the question "...now, and in the near future...", the RHC report focused mainly on products in computing, timing, sensing, and imaging already on the market or in development (i.e. beyond TRL6) although it did also cover some initiatives at earlier stages of development and their potential future governance requirements. It was clear from discussions with stakeholders that innovators expect quantum technologies, beyond a 5–10-year time frame, to deliver much more transformative applications than those we can envisage today. The challenge is to ensure that governance-related decisions taken in the next 5–10 years will ensure the safety, quality and efficacy of currently emerging quantum related products and services, without unnecessarily inhibiting their future potential, or the potential of the significantly more transformative applications of quantum technologies that may emerge on a longer timescale. That is to say, decisions should follow the principles for innovation and its governance of proportionality, adaptation, balance, and responsibility.

Evidence of the use of the PAGIT Framework

An emphasis on product-based governance. RHC's report on Regulating Quantum Technology Applications proposed that regulation should target the applications of quantum technologies, rather than the platform technology itself[74]. Stakeholders consulted for the report were uniformly in agreement with this focus. This advice also concurs with the Digital Regulation Cooperation Forum (DRCF) 'technology neutrality' approach: the regulators do not regulate a technology as such but instead the products and services built on the technology[75]. Recommendation 1 of the report calls for the development of application-specific (i.e. product-based) regulatory frameworks that are "adaptable and proportionate to the properties of individual innovations and their stage of development".

Role for standards and guidelines in future governance systems. The report also notes that, at early TRLs, governance decisions should be based on pre-regulatory standards and guidelines rather than 'hard law' regulation (see Section 3.3 and Figure 3). Some quantum-related products, for example sensing/diagnostic tests, are to some extent incremental innovations and will be covered

74 RHC (2024) *Regulating Quantum Technology Applications,* p 21. https://www.gov.uk/government/publications/regulatory-horizons-council-regulating-quantum-technology-applications

75 Digital Regulation Cooperation Forum (DRCF) (2023), Horizon Scanning and Emerging Technologies project team: *Quantum Technologies Insights Paper.* https://www.drcf.org.uk/publications/papers/quantum-technologies-insights-paper/_nocache

by governance systems already in place to control such products but there may be cases where existing regulations will need to be adapted to meet the needs of the innovative products, for example, through adaptation of post-regulatory standards and guidelines. Recommendation 3 of the RHC report highlights the need to provide foresight of future governance requirements as part of product development, in the short-term (1-3 years) for products beyond TRL 6 and in the longer-term (5-10 years) for products at TRLs 1-4. Recommendation 6 proposes that innovators and regulators should embrace pre-regulatory behavioural standards, including an RI standard, to ensure effective governance of quantum products without prematurely resorting to legally-based regulation.

Recommendations 9 and 10B highlight the need, among regulators and innovators, for a better understanding of the future roles to be played by pre-regulatory and post-regulatory standards and guidelines in the future governance of quantum technology developments, both nationally and internationally.

Distinguishing between disruptive and incremental innovation. The report makes several recommendations on the relative role of standards, guidelines and regulations depending on the stage of development of the innovation, the extent to which it is disruptive or incremental, and for which companies at which stages of technology development it will be most disruptive. Recommendations 1(A), 1(B) and 1(C) in RHC's report advise that:

- For potentially transformative innovations at early TRLs, the regulatory framework should be proportionate and flexible.
- For incremental innovations at early TRLs, the focus should be on finding the most appropriate regulatory precedent that fits best with the properties of the quantum innovation.
- For both incremental and disruptive innovations at later TRLs, the government should support the use of a range of regulatory options and choose the most appropriate domain-specific regulations on an application-by-application basis.

A commitment to Responsible Innovation (RI) practices. RI (see Section 3.5) features in several of the recommendations of the RHC report, specifically:

- Recommendation 1(A), advising on the treatment of transformative innovations at early TRLs, recommends that RI should become expected best practice.
- Recommendation 6, in the context of the UK Quantum Standards Pilot Network, proposes the development of behavioural standards, particularly RI practices, in early product development stages to ensure effective governance of quantum products without prematurely resorting to legally-based regulation.
- Recommendation 7 proposes government procurement of quantum products and services should include a statement on RI, extended where practical to all companies participating in a value chain.
- Recommendation 10(D), in relation to the Department for Science, Innovation, and Technology (DSIT)'s support for the policy environment, recommends that all regulatory initiatives, and their implementation by companies, conform with RI approaches, e.g., to ensure that data is used ethically and for societal and environmental benefits.
- Recommendation 14, on quantum computing, advises DSIT to work with industry to establish RI practices within its governance frameworks and to include specific components for quantum computing and cryptography, to mitigate current and future risks and to foster public trust in the technology.

Conclusions

The RHC report on quantum technologies is an example of the application of the PAGIT Framework in a technology domain unrelated to the one where it was developed. Feedback from quantum-related innovators, as part of the RHC's publication process, indicated that this has been helpful and informative. Its application to quantum technologies has also prompted more in-depth thinking around the 'product vs. process' distinction, the categorisation of innovations as 'disruptive or transformative' and 'incremental', and the need to understand the future roles of standards and guidelines and how they can best be deployed in different technology domains.

5.3 Manufacture of high value chemical intermediates

Background

This case study[76] clarifies how business model and value chain analysis, linked to an understanding of the disruptive potential of innovative technologies (both key components of the PAGIT Framework), can be helpful in guiding policy decisions on the governance of innovative technologies. The context was the increasing concern of governments to reap the benefits of the basic research that they fund, particularly the highly significant benefits that can emerge from successful translation of a disruptive innovation. For that to succeed they will need to have a better understanding of the nature of disruptive innovation itself, the circumstances that can stop it in its tracks or lead companies to migrate to another government's jurisdiction, and where in an overall value chain to focus policy attention. Evidence was drawn from an understanding of sectoral innovation systems in engineering biology, particularly the development of high-value intermediates for the chemical industry.

76 Tait, J. & Wield, D. (2019): Policy support for disruptive innovation in the life sciences, *Technology Analysis & Strategic Management*, DOI:10.1080/09537325.2019.1631449.

Evidence of the use of the PAGIT Framework

Two sector-related insights were addressed:

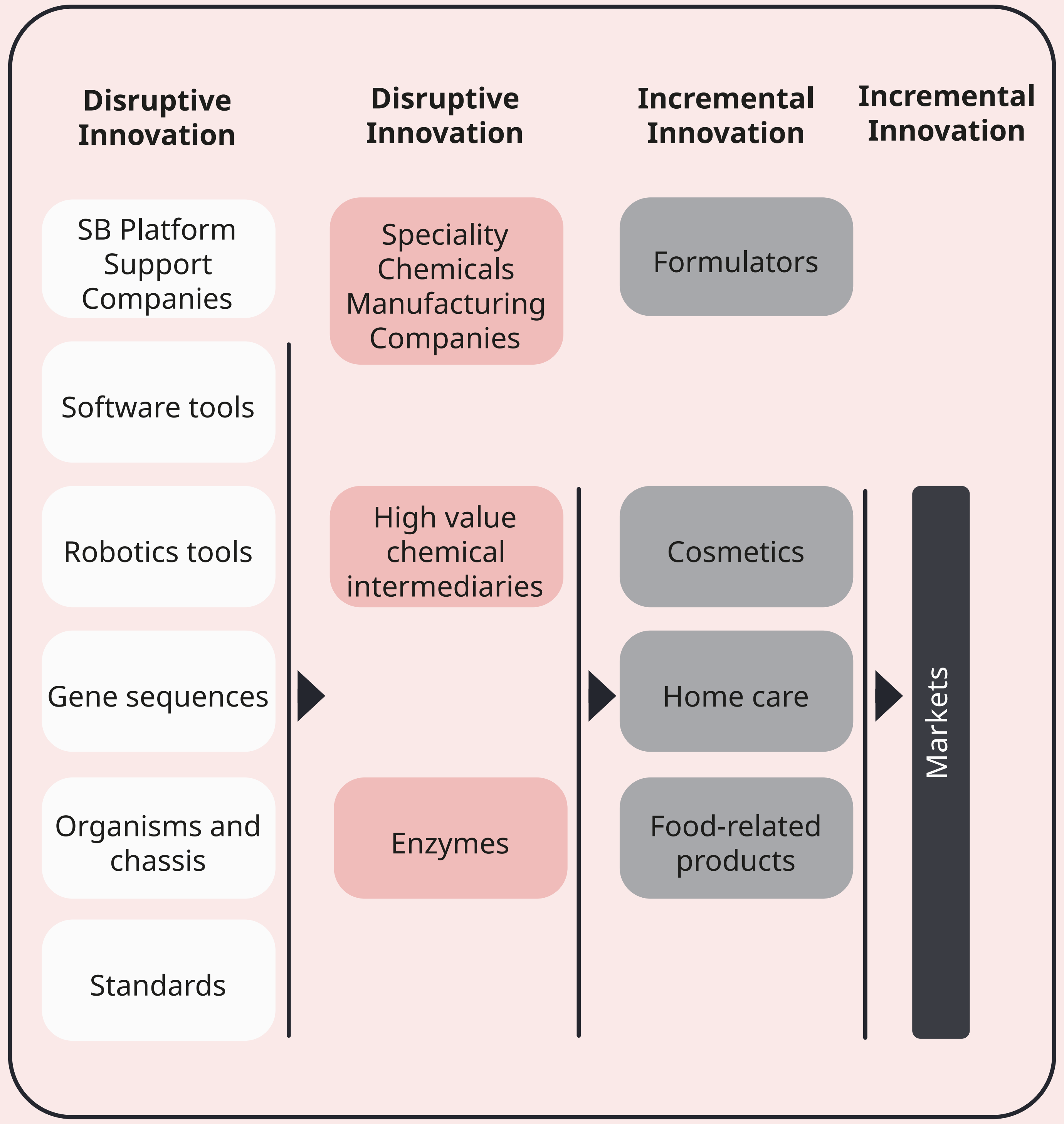
1. An innovation that is disruptive of the business model of one industry sector can be incremental for another.

The example described in Section 3.2 was the agro-biotechnology sector where, despite the fact that the disruptively innovative GM technology was least disruptive for the seeds sector, regulatory system decisions guided its development into the agrochemical sector, for which it was most disruptive, resulting in a less favourable climate for innovation.

2. An innovation can be disruptive for some of the sectors/business models contributing to an overall value chain, and neutral or incremental for others.

Examining these issues through the lens of the industrial biotechnology manufacturing sector, Figure 5 shows the four sectors involved in this value chain: synthetic biology platform support companies; specialty chemicals manufacturing companies; formulators; and markets (the final business-to-consumer sector including supermarkets and other retail outlets). New engineering biology developments are disruptive of the business models of the two upstream sectors, but incremental for the formulators and markets who are using the same chemicals in similar ways in their manufacturing and distribution processes. The latter could benefit financially from selling a more environmentally sustainable product to their customers, an example of how innovation could improve the competitiveness of a company without disrupting its business model.

Figure 5: Industrial biotechnology value chains



Responding to the first issue addressed by this case study, petrochemicals-based chemicals manufacturing companies are now being replaced by companies with business models already based on large scale fermentation and brewing, producing enzymes, food and drinks for human consumption alongside smaller companies entering this sector. There were no regulatory hurdles preventing this shift so it is happening naturally and enabling the innovative technology to be developed by the sector for which it is least disruptive.

This illustrates how the PAGIT Framework supports understanding of how to deliver successful disruptive innovation, focusing on the interactions between innovative technology developments, the business models of incumbent companies and of potential future companies, and the value chains to which they contribute. It attempts to foresight future company behaviour and innovation outcomes based on knowledge of the elements of the innovation ecosystem within which they are embedded.

The advice to policy makers based on this analysis was:

1. Identify the target areas where the innovation concerned is expected to have a disruptive impact and the high-level policies to which it is relevant (e.g., net zero, biodiversity, and the circular economy);
2. Map the relevant value chains noting the sectors, the types of companies and the scale of the companies involved in them (see Figure 5);
3. Consider the extent to which the expected innovation will be disruptive or incremental for the companies involved in the current value chain, whether they will be willing/able to incorporate the innovation into their current business models or displace them with a new one, and what is likely to be the outcome of these decisions;
4. Identify any gaps in future value chains that are likely to prevent development of the innovation or to divert activity to a different value chain;
5. Consider what sector-specific policies can support the value chain to deliver 'higher-level' policies.

These issues are suggested as the basis for a dialogue between policy makers, innovators, and incumbent companies, contributing to planning for future innovation governance and support policies.

Conclusions

This case study expands on the implementation of the PAGIT Framework, as described in Section 2, focusing on the process of scoping the value chain and the business models of the companies involved in taking an innovative product from proof-of-concept to products on a market. This is essential information as a basis for later decisions on choice of regulatory or governance system and, beyond that, contributing to delivery of UK government priorities related to supporting the national economy (while also delivering environmental and health protection).

5.4 Scottish salmon farming: optimising its contribution to climate and environmental policies (such as net zero and biodiversity)[77,78]

Background

This case study is based on a report by the Innogen Institute to address the Scottish Government's ambitions to play a significant role in sustainably feeding a growing population, minimising human contributions to climate change, and halting and reversing biodiversity loss.

Salmon farming is seen as an important contributor to all three areas, positively and/or negatively, and insights from the PAGIT Framework proved useful in indicating where, and how, a circular economy approach, along with innovative technology initiatives and an appropriate governance ecosystem could contribute to meeting broader environmental and health-related policy objectives.

Fish-based protein in human diets has a considerably lower contribution to global warming than beef or sheep production and, given that most wild-capture fisheries are either close to, or exceeding, their sustainable exploitation threshold, greater fish consumption will need to rely on aquaculture.

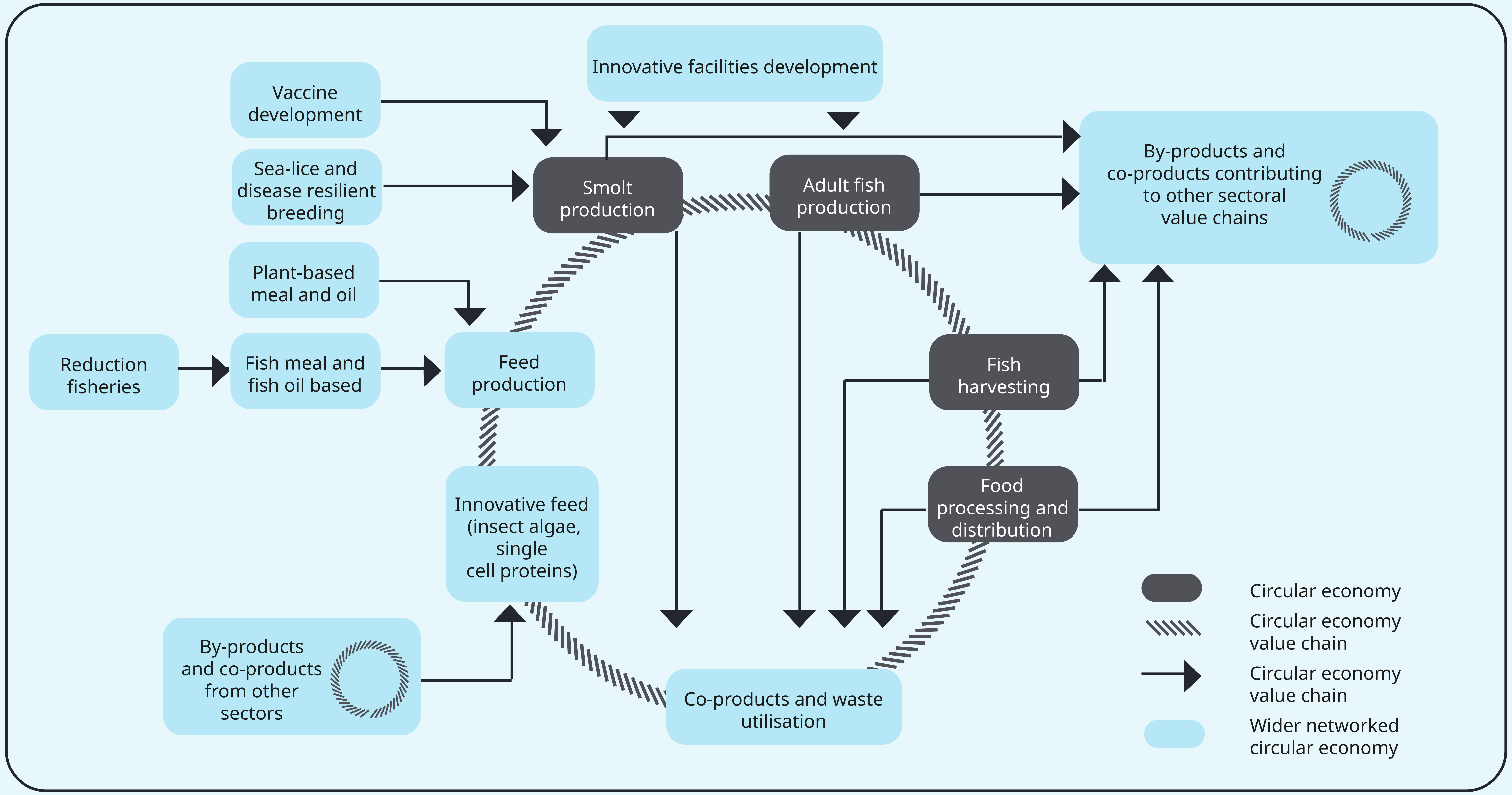
77 McGoohan, A., Tait, J., Raybould, A., Parris, S., and Hammond, K. (2021) *Fish farming in Scotland: optimising its contribution to climate and environmental policies*. (https://www.innogen.ac.uk/sites/default/files/2021-08/Scottish%20Aquaculture%20Innovations_OU%20Scotland%20Report_18.08.21.pdf)

78 Tait, J., McGoohan, A., Raybould, A., Parris, S. and Hammond, K. (2021) *Fish Farming in Scotland: Optimising its contribution to climate and environmental policies*. Policy Brief. https://www.innogen.ac.uk/sites/default/files/2021-10/Innogen%20Policy%20Brief_Salmon%20farming%20in%20Scotland.pdf

Evidence of the use of the PAGIT Framework

The report took a systemic, circular economy, approach to delivering the optimal combination of technology innovation and policy initiatives across the aquaculture value chain. To do so, it drew on elements of the PAGIT Framework related to the analysis of value chains and innovative developments relevant to the delivery of policy objectives (supporting a circular economy, mitigating biodiversity loss, and meeting net zero objectives). Figure 6 illustrates an aquaculture value chain involving innovative technologies, envisaged as part of a circular or networked bioeconomy[79]. Here the PAGIT Framework was useful in analysing and exploring issues relevant to the delivery of net zero government policies, in this case through innovative fish feed ingredients (given that aqua-feed accounts for more than 90% of fish to farm-gate global warming potential and is the most expensive component of aquaculture production).

Figure 6: The circular economy value chain/ network and the role of innovative technologies for Scottish salmon farming



79 Tait, J., Raybould, A., Flight, M.H. and McGoohan, A. (2023). Circular and Net-worked Bioeconomies for Net-Zero Food Production: There is Nothing Magic about Circles. *Circ.Econ.Sust.* (2023). https://doi.org/10.1007/s43615-022-00247-w

The report considered what a supportive innovation policy ecosystem would need to include to deliver the potential economic, health, and environmental benefits by the target date of 2045. It proposed relying on quick wins, technologies that are already in the early stages of development, and the design of favourable circular economy and policy/governance environments that encourage rapid identification and adoption of the technologies that can deliver optimal outcomes across the entire aquaculture value chain/network. This PAGIT based approach to the analysis of the aquaculture value chain/network and support for innovation led to the following policy recommendations:

1. Policy and economic incentives for aqua-feed innovation (both protein and omega-3 oils) will have the greatest impact over the shortest timescale. The biggest challenges in this area are supporting scale-up of feed production to meet future market needs, and providing policy and economic incentives for feed producers to incorporate these new ingredients in their feed formulations while they are in competition with cheaper, less sustainable ingredients.
2. All policies, including those relevant to non-feed innovations should take account of the whole innovation landscape and interactions between technologies, policies, governance/regulations, and markets when considering priorities relevant to innovation and its governance.
3. Life cycle analysis (or an equivalent approach) should be used to prioritise support for single innovations or combinations of innovations that will have the greatest impact on both climate change and biodiversity objectives.
4. A future-oriented approach to policy development should be adopted across all areas, scanning for future innovation opportunities and emerging commercial, governance, or consumer-related incentives or barriers to adoption of innovations.
5. A strategic, systemic framework like PAGIT, taking account of the entire value network (see Figure 6) and the interactions among businesses and policies, will be needed to deliver outcomes that maximise Scotland's contribution to improving the sustainability and environmental impact of fish farming and outcomes that are internationally competitive.
6. A public communication strategy should be in place to support stakeholder understanding of the value of innovative technologies in meeting widely agreed societal objectives, such as net zero, circular economy, and preventing biodiversity loss.

Conclusions
This case study is included here as an example of value chain analysis in line with the PAGIT framework and its ability to contribute to policy developments in relation to innovation. However, these policy initiatives will not be sufficient on their own to deliver the required transformation of the innovation landscape. That would require an equivalent contribution based on a further PAGIT-style analysis of the governance systems in place for the technologies involved.

5.5 Responsible Innovation (RI) along a value chain

Background

This case study focuses on the implementation of 'PAS 440:2020 Responsible Innovation – Guide', based on a project funded by Innovate UK[80]. The project included collaborations between companies involved at different stages in the progression of the single cell protein (SCP) product, from the initial feedstock producer, through the company developing the SCP, feed testing laboratories and feed formulators, to a supermarket chain. It presented an opportunity to study adoption of the RI Framework (Section 4) by companies at different translational stages in the value chain, supporting the development of innovations that contribute to the economic and environmental sustainability of the animal feed sector. The project considered technology-specific responsibility but not company-level, social responsibility (Section 3.5) and was led by the SME producing the SCP. The objectives of this work were to trial the guidance in PAS 440, and to identify the social, environmental, and health-related benefits and risks of the SCP, along with governance elements and value chain elements, at various points along the value chain.

80 ISCF Future Food Production Systems grant, 48629.

Evidence of the use of the PAGIT Framework

The PAGIT-related elements to be considered here were:

- How the nature of the SCP product evolved along the value chain;
- The extent to which the product would be disruptive for the various companies concerned;
- Where in the overall value chain that disruption would be experienced; and
- How knowledge of these factors in the context of RI did, or should, influence company decision making.

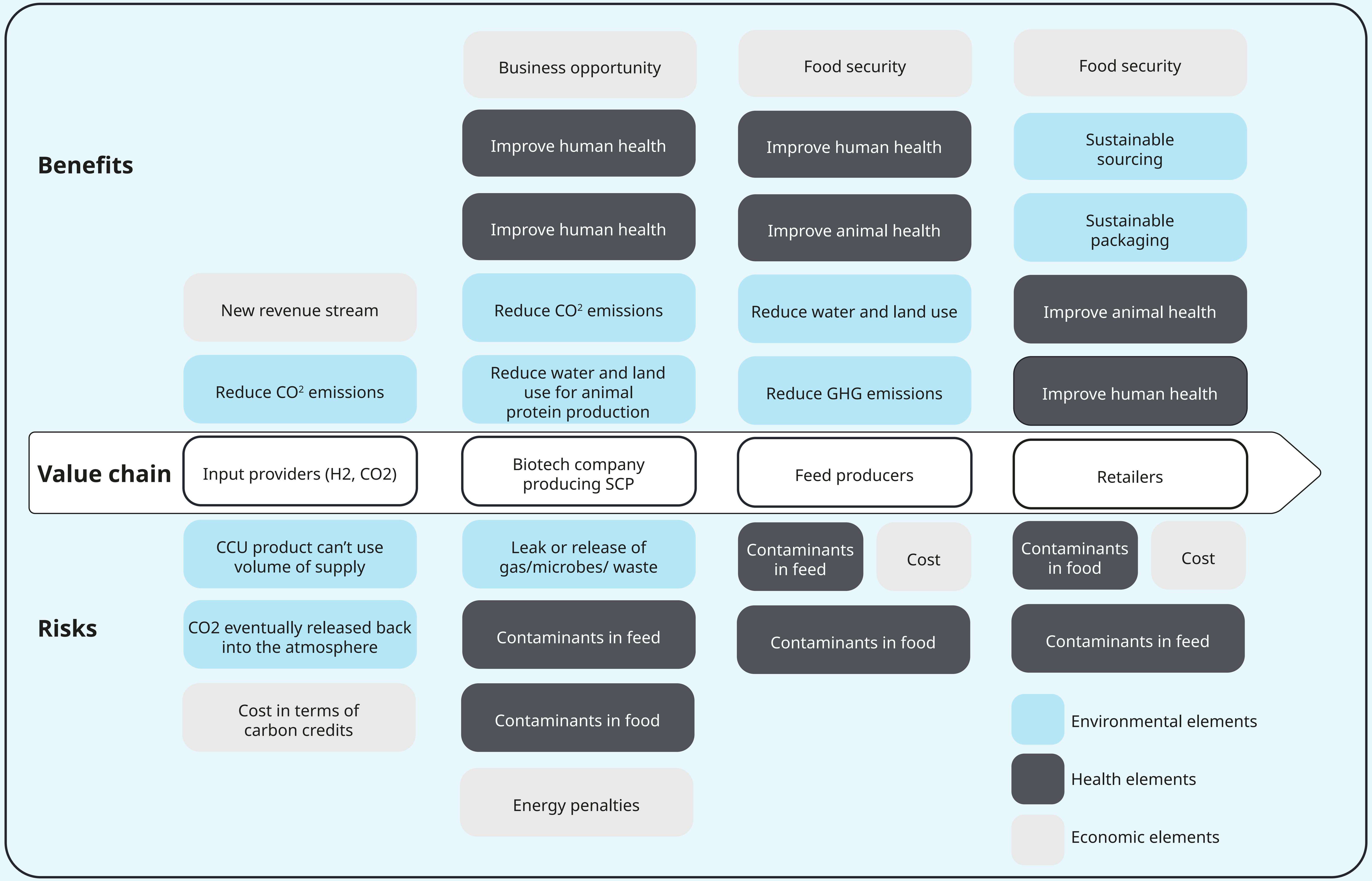
Analysis of the evolution of the product along the value chain revealed that the nature of the 'product of concern' was different for each partner and completion of the RI Framework (Table 1) was different for each company, specifically:

- For the CO_2 input provider, the focus was on the CO_2 itself;
- For the SCP producer it was the SCP;
- For the feed producers it was the final formulated animal feed; and
- For the supermarket chain it was the food product on its shelves (salmon).

Figure 7 summarises how company perspectives on RI-related issues changed along the value chain of the product and thus how different the RI analysis based on Table 1 looked for each company. The table became a very dense source of information, useful for the company that developed it as an up-to-date summary of all the RI-related information held by the company. While those who developed it would become familiar with its content, it was not a good communication tool to make others aware of how the company was contributing to its RI-related commitments. Figure 7 is one of a series of diagrams developed as an aid to communication in this context[81].

81 Monica Hoyos Flight, Joyce Tait, Theo Chronopoulos, Monica Betancor, Pauline Wischhusen, Emily Burton, Helen Masey O'Neill, Kim van der Heul, John Hays and Peter Rowe (2024, in press). Analysing Responsible Innovation along a value chain – a single-cell protein case study. *Engineering Biology.* ID: ENB2_12031; https://DOI.org/10.1049/enb2.12031.

Figure 7: Value chain perspectives on RI-related risks and benefits of the production and use of the SCP*.



*Items closest to the central line were most important to the company

Conclusions

This case study illustrates the potential of integrating RI formally along a value chain to help value chain partners (VCPs) to be more strategically aligned and support the translation of innovative products from proof-of-concept to market. This would also contribute to identifying consumer and VCP requirements, foreseeing future benefits and risks, and adapting the development of new products or technologies accordingly.

This case study explored in detail elements 7 and 8 of the RIF (Table 1), 'value chain elements' and 'regulatory elements' respectively. The whole value chain approach (Figure 7), enabled the VCPs to understand better the properties of the SCP and its role in their business models, to appraise its contribution to their own RI-related agendas, and to appreciate more clearly how this area of innovative animal feed development can be better supported in future.

This case study also contributes to future thinking about how the PAS 440 approach can be implemented and how it can usefully be adapted and/or complemented by bringing in additional concepts and considerations, particularly those related to managing and improving the translational ecosystem for innovative technologies.

Chapter six

Innovative technologies and their governance

The stimulus to develop the PAGIT Framework arose from the experience of seeing attempts to deliver innovative products and services fail because of confounding governance-related factors that either delayed decision making or created unnecessary or inappropriate hurdles along the path to a final product or service. The problem was most serious for disruptive, transformative innovations with most to offer in terms of societal, environmental, health and economic benefits. It was also frequently the case that, given these expected benefits, significant amounts of funding, publicly and commercially sourced, were being committed to supporting innovation in these domains by funders who were unaware of these governance traps. The PAGIT Framework responds to this dilemma by finding ways to adapt problematic governance systems or create new governance systems that are proportionate and adaptive to the needs of innovative technologies, identifying the most important factors to be taken into account in planning future pathways to adoption and use. The framework was gradually built up in the period before the publication of the PAGIT reports (Sections 2 and 3), and each application of its concepts since then has added further insights (Sections 4 and 5).

A major challenge throughout this period has been to introduce and use clear and consistent language. Many of the systemic concepts and interactions embedded in the PAGIT Framework are defined or used differently or inconsistently in different academic disciplines or innovation contexts and are also used loosely in common language. Our approach has been to define clearly how we are using a particular term (Annex 1) and to stick as closely as possible to that interpretation throughout the report.

Coming up to date, the 2023 UK Government Review on Pro-innovation Regulation of Technologies refers to the need, in an age of ultra-rapid technological change, for regulators to adapt to enable the safe and rapid introduction of beneficial emerging technologies[82]. In order to do that well, regulators will need to have a different, more nuanced understanding of the innovators' perspectives and vice versa. This report treats these two perspectives separately, the innovators' perspectives in Section 3.2 and Figure 1 and the regulators' perspectives in Section 3.3 and Figure 3. However, the benefit from the PAGIT framework lies in the combination of these perspectives within a sector-based analysis.

82 HM Government (2023) *Pro-innovation regulation of technologies review: Cross-cutting and growth duty recommendations.* https://assets.publishing.service.gov.uk/media/655cd10ad03a8d001207fdfd/_8243__GCSA_Pro_Innovation_cross_cutting_Report_PDF.pdf

6.1 Choosing the basis for governance-related attention – product, not process.

The starting point of any analysis should be to identify and bring to the foreground the innovative products or services to be given particular governance-related attention. References to 'regulating gene editing', 'regulating AI' or 'regulating quantum' should flag up a need to re-focus the analysis on products or services themselves and their properties, including both benefits and risks. See for example the RHC reports (Sections 5.1 and 5.2) and the UK Government Pro-innovation Regulation (Section 2.1) reviews.

For genetic technologies (Section 5.1), in the EU, a process-based approach to their governance has been well embedded since the 1980s and is reinforced by the UN Convention on Biological Diversity and its Cartagena and Nagoya Protocols. The RHC Report on Genetic Technologies[83] attempted to demonstrate how the UK governance approach could be adapted to the products of the new genetic methods now being introduced, but it may be difficult to convince some regulators that this is either possible or desirable.

83 RHC (2022) *Report on Genetic Technologies*. https://assets.publishing.service.gov.uk/media/62c809d5d3bf7f3004d17f6f/regulatory_horizons_council_report_on_genetic_technologies_july_2022.pdf

In addition, governance-related discussions now taking place for quantum products and services (Section 5.2) may benefit from a smoother transition to a proportionate and adaptive governance approach that optimises the contributions of legally based regulations, standards, guidance, codes of practice and parallel innovation promotion policies.

It is also important to note that, even though the primary focus of governance-related actions is the product or service and its properties, some features of the innovation process or technology platform should not be ignored. It will be the source of the benefits expected from the new products or services, but may also introduce novel hazards into the products or services themselves, or in manufacturing processes, and these will need to be addressed by the governance system.

Decision making about the appropriate choice of regulatory precedent - particularly for disruptive innovation for which there may be no obvious precedent - is largely unexplored territory, and 'product vs. process' is only a small part of a much bigger picture.

6.2 Disruptive and incremental innovation

Innovators themselves will be best placed to understand the nature of the innovation process they are leading, and the extent to which its influence on their business models and those of value chain partners will be disruptive or incremental. However, those involved in the governance of innovative technologies will also need to understand these differences and how they should be taken into account in the design of future governance systems.

Disruptive innovation
For disruptive innovation:
A strategic approach to the choice of governance system should be based on the capacity of existing industry sectors (or an entirely new sector) to deliver the innovation while continuing 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 governance approach. During TRLs 4 - 6, by which stage there should be a good understanding of the properties of the products or services, regulators and innovators should discuss the following questions:

- To what extent will the innovative developments lead to disruption of existing company business models?
- For which companies in which sectors will it be least disruptive?
- What is the governance system pertaining to that sector?

The most straightforward case is where an innovation could potentially be developed by more than one industry sector, with different degrees of disruption of business models for each sector. The recommendation would be to choose the governance system that applies to the sector for which the innovation would be least disruptive, potentially converting the innovation to the 'incremental' category. Any necessary regulatory adaptation could then be achieved by changes to post-regulatory standards and guidance, rather than requiring the much more demanding changes to a legally-based regulatory system.

More complex cases would be those where innovative products or services will be disruptive of the business models of several different sectors, with good reasons why they are 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 entirely new business sectors with no clear governance precedents.
In such cases, at TRLs 4 – 6, standards bodies and regulators could collaborate with industry and other stakeholders on the development of pre-regulatory standards and guidelines to ensure the safe and effective development of products or services while evidence is gathered about their properties.

Accepting that, to preserve future adaptability in governance systems, legally based regulations should be avoided where possible in favour of standards and guidelines, there would then be the following governance options:

1. There is no risk-based justification for a legal regulatory system for the products or services in question, and effective governance can rely on standards and guidelines already developed, and adapted where necessary. In some cases, it may be necessary to subdivide products or services into separate classes so that only some of them receive legally based regulatory oversight.
2. There is a need for a legally based regulatory system for the relevant products and services, and based on the development of pre-regulatory standards and guidelines and the knowledge gained, there is the possibility of applying an existing regulatory system. That regulatory decision is likely to expose a need for adaptation of the regulatory system to ensure that the standards and guidelines developed from TRL 6 onwards are proportionate to the properties of the new products and/or services.
3. If, even after further development of pre-regulatory standards and guidelines no 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. This is likely to be a very costly and time-consuming option with considerable costs and delays for the sector concerned.

In the above processes, there will be an initial period where the relationship between innovators and regulators can be one of dialogue and mutual accommodation, e.g. through a regulatory sandbox, up to the point (TRL 5-6) where a decision will be made about which regulatory system should be adopted. From that point on the relationship will be more distant (as is usually the case between regulator and regulatee).

Incremental innovation

Most innovation is incremental and fits well within the innovator's business model, and most of the governance of incremental innovation is likely to be routine. However, there are occasions when an innovation that would be classed as incremental by our definitions does meet regulatory hurdles that would be seriously inhibiting and where adaptation would be needed. An example of successful adaptation for a set of incremental innovations is the decision of the US Food and Drug Administration to change the guidelines for the conduct of clinical trials for new antimicrobial drugs, which brought down the cost of their development by ~50%[84], meaning that this regulatory hurdle was no longer seen by the pharmaceutical industry as inhibiting antimicrobial drug development. Adaptation of post-regulatory standards or guidelines can have a rapid and powerful impact on the pace of innovation and should be considered more widely for such cases.

84 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.

6.3 Orchestrating the governance instruments.

The following text is taken from the Preface to the PAS 440 Guide[85], but it is just as relevant to the PAGIT Framework as a whole as it is to responsible innovation.

"We have all heard someone playing a musical instrument out of tune. It sounds pretty unpleasant. When two people play together, and they are not properly in tune, it sounds even worse. The more people playing, and the further separated their tuning is, the worse it gets. A large modern orchestra can consist of over 100 musicians, depending upon the piece they are playing. That many people playing out of tune would sound truly awful which is why, before concerts, we hear them honing their tuning to be perfect. It is customary that everyone tunes to the note A (above middle C) played on the oboe. The frequency of the note the oboe plays, concert pitch, is 440 Hertz. Only when everyone's playing is rooted to the same tuning note (usually 440 Hz) does it sound good.

This is the inspiration for the number of this Publicly Available Specification (or PAS) on responsible innovation. Just as the different sections and instruments in an orchestra only play beautifully together when they are tuned to the same note, so too is innovation more successful when the different stakeholders in a value chain act in an agreed and coherent way. New products, services and processes that work for all parts of a supply chain, and are accepted by wider society, have the potential to flourish. They are well positioned to serve the interests of companies, suppliers and customers and citizens. Where these conditions do not apply then the new products, services and processes are more vulnerable, and far more likely to fail."

The value of the PAGIT Framework as a procedure for guiding the governance of innovative products and services is based on the combination of elements that it takes into account (the variety of instruments in the orchestra and the tunes they can play): business models, value chains and the technology readiness levels reached by products and services; the extent to which an innovative product or service is likely to be disruptive or incremental; the relative roles of standards, guidelines and legally-based regulation in the governance of innovative products and services; and responsible innovation and how the concept changes at different points along a value chain. None of the insights gained by developing and using the PAGIT Framework would have emerged from a mind-set conditioned by a starting point in a process- or platform-based approach to the governance of innovation.

Sections 5.3-5.5 demonstrate the importance of understanding the business models of companies contributing to the overall value chain that encompasses the development of an innovative product or service and particularly of understanding the extent to which incumbent business models will be disrupted by the new products or services and where in the overall value chain that disruption will occur (Section 5.3). This understanding can be used to guide decision making on giving a preferential role to standards rather than legally-based regulation in early TRLs, and considering critically whether legally-based regulation will be required in later TRLs.

An important tool, worthy of greater attention in future, is the deployment of technological innovation itself to detect and eliminate or minimise specific hazards in a product or service, rather than adopting governance instruments that may be more restrictive of its future development and use. Case study 5.1 gives as an example the role of gene sequencing in identifying cases where problematic genetic changes might have been made to an organism and then in eliminating that problematic change.

85 Mason, P. (2020) Preface. *BSI PAS 440:2020 Responsible Innovation – Guide.* ISBN 978 0 539 04613 7

The contribution of standards to the PAGIT governance approach lies partly in their diversity and ability to cope with a broad range of circumstances (e.g. covering products, services, manufacturing and organisational behaviour), partly in their adaptability 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. It is not clear whether there is more consultation with stakeholders during the development of standards or regulations; there is considerable variation across sectors. However, there will be inevitable differences in style and outcomes where the regulator is in charge (regulations) and where industry takes a leading role (standards). An approach that balances these two influences, in different proportions, according to circumstances, at different TRLs, as suggested here, is likely to deliver more optimal outcomes for both disruptive and incremental innovation.

It is also worth noting that, in Sections 5.3 and 5.5, the innovative product itself reaches TRL 9 before the end of the value chain and is then marketed through a series of further B2B transactions. In Section 5.5 the product is transformed from single celled protein at TRL 9, and then to animal feed and on to fish on a supermarket shelf, requiring additional product-related governance scrutiny, based on either regulations or standards, at each stage in the value chain.

As the examples given in this report demonstrate, the PAGIT Framework is a work in progress. Each study based on the framework has opened up new questions and insights and this process can be expected to continue. However, the fact that relevant areas of application continue to expand, and to lead to fresh insights, indicates that the foundations are strong, and further exploration will contribute to the much-needed future reforms of governance systems.

There is general agreement that the UK's future prosperity, and its ability to meet climate change and biodiversity-related objectives, will depend on successful and rapid deployment of innovative products and services across all sectors of the economy. The PAGIT Framework could make a significant contribution to ensuring that our future governance systems support these objectives.

Annex 1. Definitions

Innovation perspective

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, 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.
The term *platform* is used in this report to describe a foundational technology that serves as a base upon which other applications or technologies are developed. … a set of capabilities or systems that underpins a broad range of potential applications across various fields. It delineates a set of innovative developments with similar characteristics and hence potentially similar approaches to governance and innovation promotion.

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 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. Used particularly in business, management and policy contexts.

The term **transformative innovation** is used particularly in public-facing contexts for innovation that is disruptive of incumbent company business models or transformative of markets delivering societally or environmentally useful innovations.

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 governance framework in place, but will not lead to sectoral transformations.

Governance perspective

Governance describes a means 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). The PAGIT project includes formal legally based regulation of new technologies, other 'softer' approaches using standards, guidelines, codes of practice, policies and any other mechanisms by which authority and influence on decisions are exercised.

Regulation is an important component of the governance system and is defined as the act of rule-making by a government or other authority in order to control the way something is done, the way people behave or the safety-related properties of products and services (https://www.collinsdictionary.com/dictionary/english/regulation). In the PAGIT project it mainly refers to regulations with legal authority exercised by a state or international body. However, the term is often used loosely in government publications and other reports to include all aspects covered by the above definition of governance. In this report we have mainly, but not completely consistently, used 'regulation' in the 'hard law' sense of this definition, departing from that approach where the point is related, for example to a report that uses the term in the broader sense and where the context should be obvious.

BSI describes a **standard** as a "document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context"; and *consensus* as "having general agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments" [86]. Consensus need not imply unanimity (http://www.ses-standards.org/?58).

Publicly Available Specification (PAS) is a document that standardizes elements of a product or service, 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/).

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).

BSI PAS 440 describes **Responsible Innovation** as "careful consideration of, and action to address, the potential impacts of introducing a new product, service, process or business model". (https://pages.bsigroup.com/l/35972/2020-03-17/2cgcnc1?utm_source=pardot&utm_medium=email&utm_campaign=SM-STAN-LAU-PAS-PAS440-2003)

Regulatory or governance principles, as used here, carry the weight of foundational values that underlie the development of a policy or regulatory approach and that serve as the basis for a chain of reasoning. This report focuses on four principles that are seen as essential to the better governance of innovative technologies – proportionality, adaptation, balance and responsible innovation.

86 BSI (2011) A standard for standards – principles for standardisation BS 0:2011. https://www.bsigroup.com/LocalFiles/en-GB/standards/bs0-pas0/BSI-BS0-Standard-for-Standards-UK-EN.pdf

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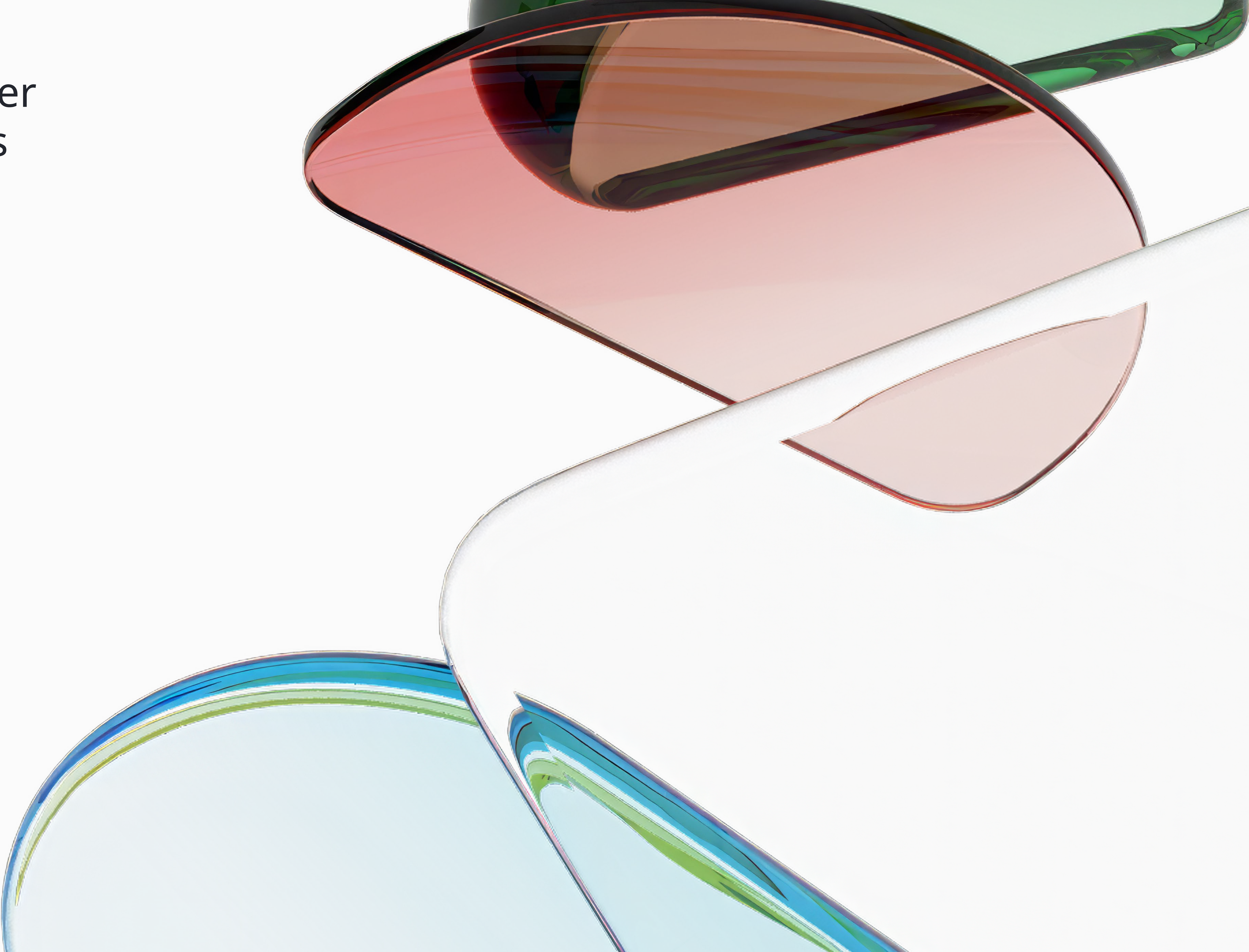

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