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Citation for published version:

Tait, E, Banda, G & Watkins, A 2017, *Proportionate and adaptive governance of innovative technologies (PAGIT): A framework to guide policy and regulatory decision making*. Innogen Institute Report, Edinburgh. <<https://www.innogen.ac.uk/reports/1222>>

Link:

[Link to publication record in Edinburgh Research Explorer](#)

Document Version:

Publisher's PDF, also known as Version of record

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PROPORTIONATE AND ADAPTIVE GOVERNANCE OF INNOVATIVE TECHNOLOGY (PAGIT)

EXECUTIVE SUMMARY

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1. Introduction

The UK Government has ambitious plans to provide financial, organisational and structural support to the UK's most innovative industry sectors. However, these investments will fail to deliver the expected benefits unless they are accompanied by targeted initiatives to make regulatory systems more proportionate and adaptive to the needs of innovative technologies. The framework developed for the PAGIT project will support improved, more evidence-based policy and regulatory decision making that takes account of the needs of innovative technologies and at the same time continues to ensure safety, quality and efficacy of the final products or processes. This approach has the potential also to contribute to the UK Government's desire to lead internationally in developing a regulatory test-bed for innovative technologies.

How we choose to regulate an innovative technology will define the future shape of the industry sectors that form around it, including the extent to which small and medium sized companies are able to thrive and grow independently of incumbent multinationals. Past regulatory choices, particularly for the most innovative technology areas have sometimes been idiosyncratic, reflecting a range of pressures from industry, policy makers, regulators and societal lobby groups. The end result has been that several regulatory systems have become complex, rigid, time consuming and, for smaller companies, prohibitively costly. In such circumstances, the innovation landscape is dominated by the business models of large multinational companies, with their preference for incremental rather than disruptive innovation. In such areas it is very difficult for a small or medium sized company to gain an independent competitive advantage based on a disruptive innovation and this loss of innovation potential will have a significant impact on the UK's national and regional economies.

The PAGIT Framework incorporates three principles to guide decision making - the EU **innovation principle** ("... to improve the quality and application of EU legislation and ... to stimulate confidence, investment and innovation") supported by the regulatory **principles of proportionality and adaptation**. It brings together the main actors in innovation ecosystems: scientists/innovators; policy makers/regulators; and citizens/stakeholders.

The key to delivering these principles lies in considering the extent to which an innovative technology will be disruptive or incremental in its impact on company business models and sectoral value chains, illustrated by two case studies: (i) Active Implantable Medical Devices (an example of incremental innovation) and (ii) Synthetic Biology and Gene Editing (an example of disruptive innovation). Abiding by these principles will also require the main actors in innovation systems to comply with the proposed **Responsibility Standard**, with two component standards on Responsible Innovation and Responsible Engagement.

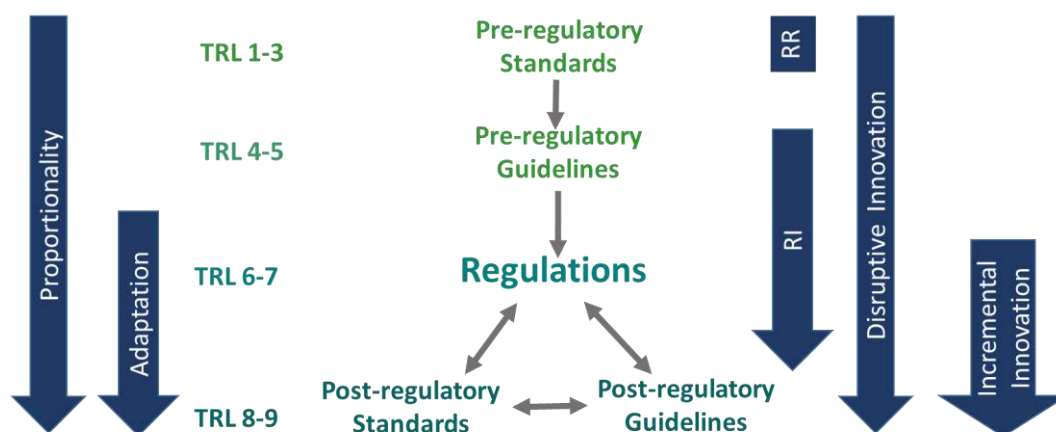
This project could also contribute to advising the UK Government on meeting the Brexit-related challenge to reconsider our regulatory systems as their administration is transferred from the current EU authorities to UK bodies.

2. A staged approach

The PAGIT Framework (Figure 1) guides decision making for innovative technologies according to the Technology Readiness Level (TRL) reached by the innovation and the extent to which it is expected to be incremental or disruptive in its impact on the business models of incumbent companies. This relates the Framework to the innovation principle and guides further decision making on the basis of the principles of adaptation and proportionality.

- For incremental innovation there will be a clear, uncontested choice of regulatory system, with post-regulatory standards and guidelines already in place. Where they are not well-matched to the properties of an innovation and are likely to constrain its future development, their adaptation can be a powerful enabler of innovation. For example, 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%.
- Disruptive innovation will be a much rarer occurrence than incremental innovation and it is also much more challenging for decision makers. There will be no clear choice of regulatory system for the new technology, or alternatively this choice may be contested.

Figure 1. PAGIT Framework

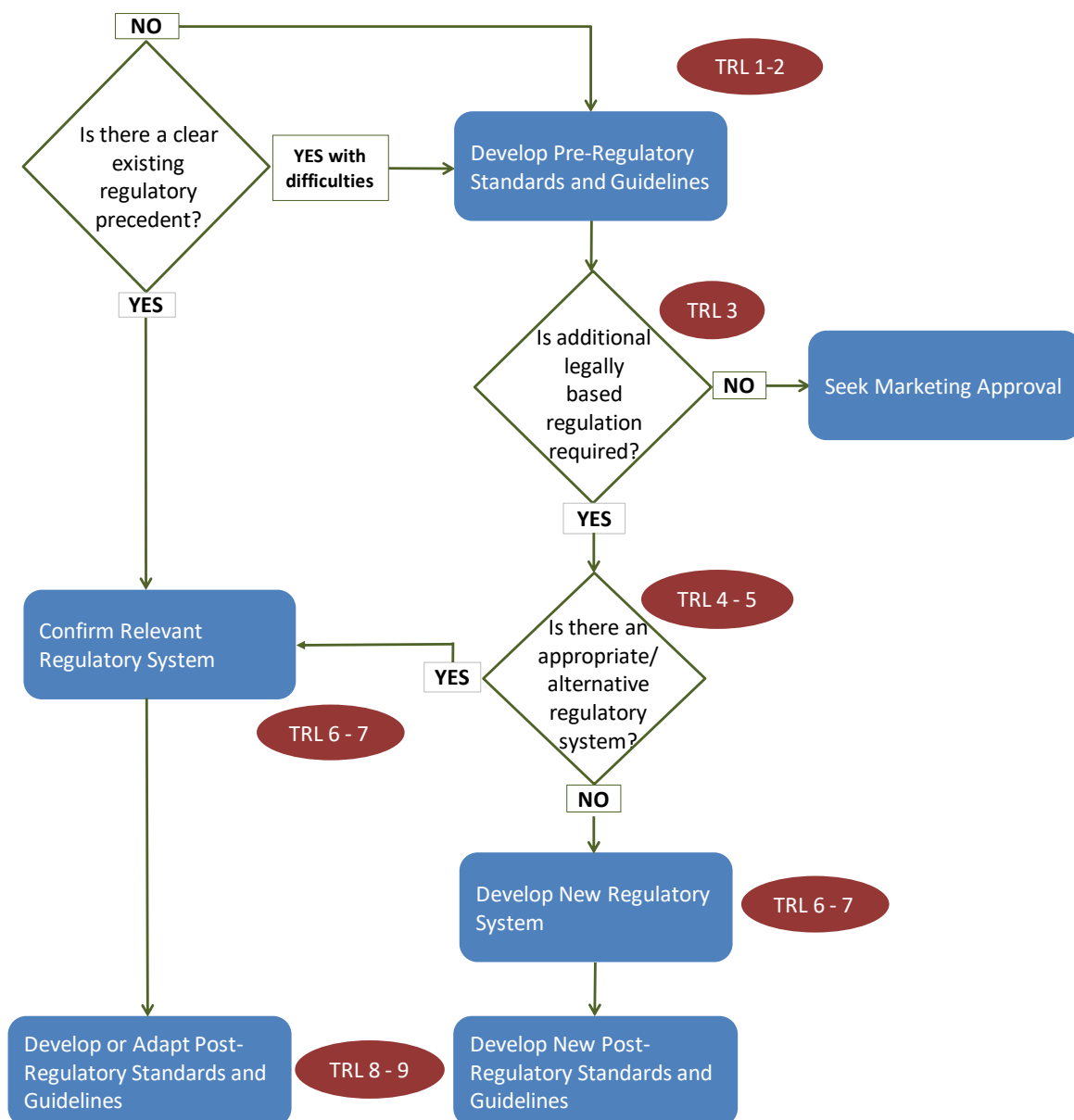


Building on this Framework, Figure 2 describes the decision processes for disruptive and incremental innovation. Disruptive innovation will require the full, staged decision making process, starting from TRLs 1 – 3, and for the much more common incremental innovation the process can begin at TRLs 6 – 7.

- TRL 1-3 (**Pre-Regulatory Standards**). Focus on aspirational or consensus standards to support understanding of the properties of the innovation, including its potential risks and benefits and how they could best be governed.
- TRL 4-5 (**Pre-Regulatory Guidelines**). From these initial standards, develop more formal guidelines that could then, if necessary, form the basis of a future regulatory system. At this point decision makers should also be open to a conclusion that the proposed pre-regulatory guidelines are sufficient to ensure safety, quality and efficacy of the innovation and that further legally based regulation is not necessary, prior to market approval.

- (iii) TRL 6-7 (**Regulations**). Either decide which existing regulatory system is most appropriate to the properties of the innovative technology or, for the most radically disruptive technologies, consider devising a new regulatory approach. Legally binding regulations should be couched in general terms relating to their desired outcome and be backed up by post-regulatory standards and guidelines.
- (iv) TRL 8-9 (**Post-Regulatory Standards and Guidelines**). Devise standards and guidelines to support compliance with the regulatory system by those involved in developing the new technology.

Figure 2. Using the PAGIT Framework for incremental or disruptive innovation



The proposed **Responsibility Standard** incorporates standards for both responsible innovation and responsible engagement, to balance the needs and perspectives of

companies, citizens and stakeholders on a more equitable basis than currently prevails. This will contribute to achieving adaptation and proportionality in future regulatory systems.

3. Outcomes from case study interviews and workshops

Project participants generally supported the PAGIT Framework approach to regulation and governance of innovative technologies. Currently regulator/innovator interactions are often in the form of advice from regulators on how to adapt a non-routine innovation to the needs of the regulatory system excluding, as proposed here, also considering how to adapt the regulatory system to the needs of the innovation. The PAGIT Framework could make a difference by encouraging regulators and standards bodies to be more open to: (i) adaptation of post-regulatory standards and guidelines to meet the needs of incrementally innovative technologies, and (ii) development of pre-regulatory standards and guidelines as a prelude to making a decision on the appropriate regulatory system to be applied to a disruptive innovation. The role of the regulator would not change in either case from that of a legally-backed authority with jurisdiction over a specific area of human activity and there should be no diminution in safety, quality and efficacy requirements of innovative developments.

The PAGIT Framework supports understanding of the complexities involved in categorising innovation as disruptive or incremental and in applying that understanding to real-world regulatory examples. This is an early step on the road to making regulatory systems more adaptive and proportionate to the needs of innovative technologies, complementing other EU and OECD initiatives. It demonstrates how one could deliver a governance approach that matches the innovation opportunities arising from 21st century science.

Active implantable medical devices were chosen as an example of incremental innovation but some of the most innovative developments are likely to require very significant adaptation of post-regulatory standards and guidelines. They will be subject in future to the requirements of the EU Medical Devices Regulation (2017), with post-regulatory standards and guidelines currently in development. This creates an opportunity for regulators and standards bodies to engage with innovators to consider how, if necessary, to adapt the post-regulatory standards and guidelines to meet the needs of innovative developments that challenge the processes in place for existing technologies.

The case study on synthetic biology and gene editing was initially classed as an example of disruptive innovation but during the project some developments were redefined as incremental. Examples of incremental innovation in this area would be development by an agro-biotechnology company of improved versions of GM crops or where a company with expertise in fermentation technology uses micro-organisms to manufacture biofuels or new intermediates for chemical manufacturing companies.

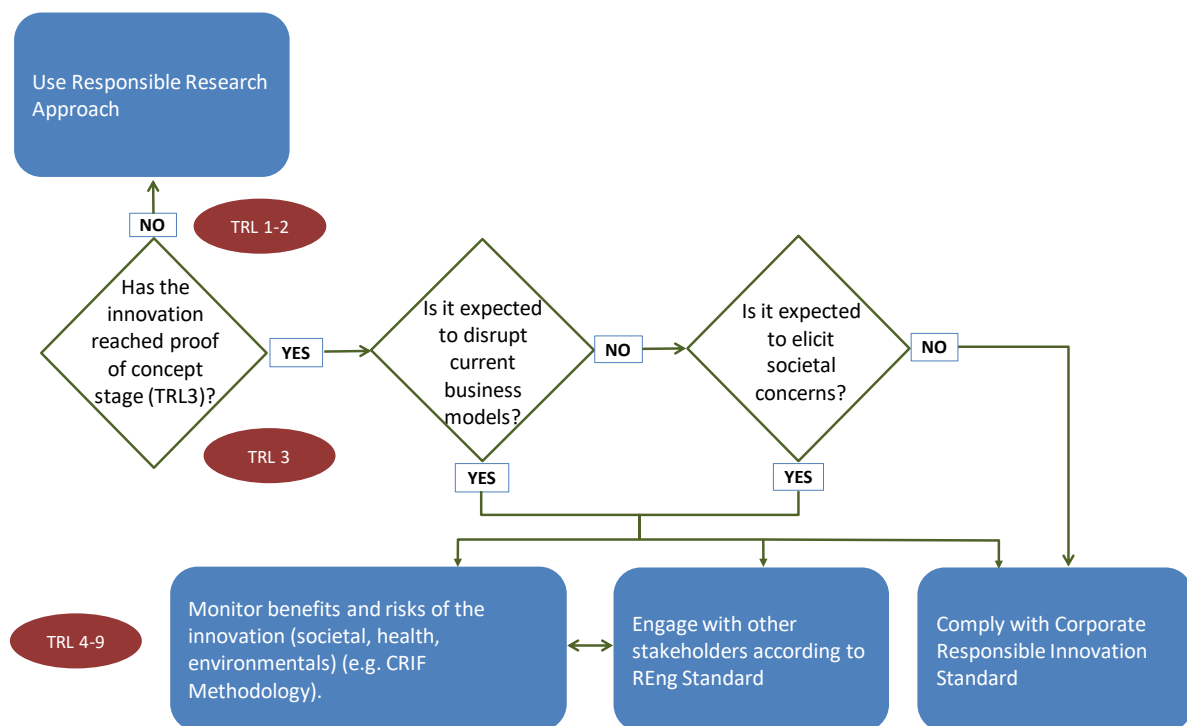
Disruptive innovation opportunities from synthetic biology and gene editing include opening up niche markets for crop-related developments that are too small to be of interest to the multinational agro-biotechnology industry sector, but that could grow to become a significant parallel sector in the bioeconomy. For these disruptive opportunities there are several potential regulatory precedents in a range of countries, none without some disagreement about its proportionality. It would be appropriate to consider adopting the full framework approach for such cases, beginning with pre-regulatory standards and guidelines at TRLs 1 – 5. For these applications project participants proposed that regulators should be

open to concluding at TRL 5 that there is no need for legally based oversight beyond pre-regulatory guidelines.

There was also support for the development of a Responsibility Standard with two elements (Responsible Innovation and Responsible Engagement) (Figure 3).

- (i) The overall Responsible Innovation Standard would include a Corporate Responsible Innovation Standard to guide a company’s general behaviour, implemented through its standard operating procedures. For most incremental innovation, no further action would be required of companies. Where a disruptive innovation is involved or where there is significant societal interest in it, companies should also monitor innovation-specific elements of the development, including societal and environmental risks and benefits, through a Consolidated Responsible Innovation Framework (CRIF) from TRLs 4-9.
- (ii) The Responsible Engagement Standard and associated guidelines would require *all* stakeholders, citizens and advocacy groups as well as industry, to engage responsibly. This is more equitable than the current approach which focuses almost entirely on responsible behaviour by companies.

Figure 3. Using the PAGIT Responsibility Standard



The PAGIT report also proposes a set of guidelines for policy makers and regulators to support their compliance with the principles of innovation, proportionality and adaptation, as increasingly required by governments.

4. Conclusions and recommendations

The report's conclusions are relevant to a broad range of innovative technologies and sectors where the UK sees itself as leading in the field. These include autonomous and low-emission vehicles, FinTech, robotics, aerospace, battery technologies, chemicals and industrial biotechnology and life sciences (pharmaceuticals, cell therapies, gene editing, synthetic biology, stratified medicine, agricultural and food technologies). The BSI could take a major role in implementing this approach, leading to more proactive involvement of standards in regulatory systems, particularly for the most innovative technologies. It could also have a major role in supporting the adaptation of UK regulatory systems to address the implications of the Brexit decision without damaging future international trading prospects.

Most elements of the Framework are not in themselves novel and many are elements of at least some current regulatory systems. The novelty of the approach lies in its ability to manage the systemic interactions across different industry sectors at different stages in development of an innovative technology, with different elements of regulatory systems, and different stakeholder constituencies. If the PAGIT Framework could succeed in supporting more effective management of these interactions, even to a modest degree, we could see a dramatic improvement in the value for money generated from public and private investment in scientific research.

The following further developments are proposed:

- (i) Application of the PAGIT Framework to imminent decisions in the UK on future regulation of SB and GE, building on the case study conducted here, potentially involving BSI;
- (ii) Immediate moves towards development of an overall Responsibility Standard, including Responsible Innovation and Responsible Engagement Standards, again potentially involving BSI;
- (iii) Continued involvement of BSI in the development of post-regulatory standards and guidelines for active implantable medical devices, being alert to any opportunities that arise over the next three years to adapt these instruments to the needs of the most innovative developments;
- (iv) Development of further case studies on potentially disruptive technologies to enable wider uptake of the PAGIT approach.
- (v) Development of a detailed analysis of the opportunities to use the PAGIT approach to optimise the UK's future regulatory systems for innovative technologies in the context of the Brexit negotiations.