



Executive Summary

Proportionate and adaptive governance of innovative technologies

The role of regulations, guidelines and standards

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Executive summary

Government financial support for the development of innovative technologies plays an important role in achieving the expected benefits from the UK's excellence in basic science. However, this support will fail to deliver the promised impact unless smarter, more adaptive regulatory systems are developed that are more proportionate to the levels of risk embedded in new technologies. This is particularly true of some of the technologies where the UK is identified as leading the field, such as life sciences, genomics and synthetic biology; regenerative medicine; financial technologies; and agri-science. Problems can arise because of an inappropriate choice of regulatory system to deal with new technologies and/or failure to adapt current regulatory systems to the needs of new technologies. There is a clear need to learn from past experience and to craft smarter regulatory systems that are able to incentivize innovation while still delivering safety, quality and efficacy.

These concerns about the fitness-for-purpose of regulatory systems are leading to new emphases on adaptation and proportionality in regulatory regimes, along with an 'innovation imperative' targeted at regulators. The premise of the report is that innovation would benefit from a formal consideration of the complementary roles that regulations, guidelines and standards could play in delivering the required proportionality and adaptation.

The project focused on where standards could contribute most effectively to different types of innovation (incremental or disruptive), across different industry sectors with differing experiences of regulation. The economic impact of standards would come from boosting productivity, opening up new markets, linking UK companies to global supply chains, reducing technical barriers to trade for incremental innovations, and supporting the development of more disruptive innovations. However, inappropriate, poorly specified or insufficiently adaptive standards can have negative impacts on the economic competitiveness of companies and countries, and removing these disincentives is an important part of the overall picture.

General conclusions include the following:

- Current governance systems for innovative technologies lack coherence and are in need of a new approach to guide more effective decision making.
- Where a regulatory system is imposed in the early stages of development of an innovative technology, it generally requires subsequent adaptation but proves difficult to adapt.
- Exceeding the minimum requirements of a regulation ('gold plating') can have serious negative impacts on innovation.
- One benefit of standards is the reduction of variety, increasing the economic viability of markets; however, for a disruptive innovation it may be more desirable to retain as much variety as possible until it becomes clear what the winning technology will be.

The following are a few important insights from each of the three case studies:

Personalized medicine manufacturing for autologous cell therapies

In manufacturing, there were difficulties experienced in adapting the chosen chemicals-based regulatory system to biological products and also in developing standards and guidelines for cell manufacturing. For some clinical applications, there was no regulatory system in place. The competitive nature of the industry made it difficult to persuade companies to collaborate and the resulting delays could increase risk to patient safety.

Industrial biotechnology/synthetic biology

Where environmental release of a genetically modified organism (GMO) is involved, the existing EU regulatory system will require considerable adaptation if European economies are to be able to benefit from the use of the technology. Across all applications, standards are playing important roles in synthetic biology development, but in the 'contained use' manufacturing of products using synthetic biology, regulatory adaptation is needed to make it easier to change

the organisms used in the manufacturing of complex protein molecules when new, more efficient processes become available. There is some concern about political issues stemming from an association between synthetic biology and GM technologies, and interviewees found it difficult to engage with regulators, unlike in medicine-related sectors.

Financial technology (FinTech)

The regulatory systems in this sector are very different from the other two cases, the relevant risks being financial and reputational. More than in the other cases, regulators appreciated the potential economic and consumer benefits of FinTech and there were good interactions with innovators, particularly to support SMEs. There was a move away from detailed, prescriptive rules towards high-level, broadly stated principles to set the standards for regulated firms. Future standards will include the use of technology for automated risk assessment (RegTech) and a 'regulatory sandbox' approach is being developed to help new firms navigate regulatory challenges. Regulators are also alert to the fact that big companies favour heavy regulation as it acts as a barrier to entry for others.

Framework for Proportionate and Adaptive Governance of Innovative Technologies

The report proposes a framework for conceptualizing the potential roles of standards, guidelines and regulations in the delivery of more proportionate and adaptive governance for innovative technologies to support decisions by companies, regulators and policymakers.

In developing a regulatory system for a disruptive innovation with a novel value chain for which there is no existing regulatory precedent, a staged approach has been proposed:

1. In the early stages of developing a technology, focus on Publicly Available Specifications (PASs) and/or consensus standards devised in collaboration with companies and scientists with expertise in the area.
2. As experience is gained and the future nature of innovative products and processes is clarified, adapt the initial standards and formalize them as guidelines that could then form the basis of a future regulatory system.
3. Based on these guidelines, in a more openly democratic process involving all interested stakeholders, develop legally binding regulations, couched in general terms relating to the desired outcome of the regulation.
4. Also in an open democratic process involving all interested stakeholders, devise standards and guidelines to support compliance by those engaged in developing the new technology.

For incremental innovation that fits readily into existing industry value chains and current regulatory systems, the problem is more often that the regulatory system that has built up over a period of years is insufficiently adaptive to the needs of new technologies, and can unnecessarily inhibit innovation. Here, standards can have an important role in enabling adaptation of the incumbent regulatory system so that it becomes more supportive of innovation.

Responsible research and innovation (RRI)

The report also proposes a more integrated approach to incorporating RRI (as desired by many stakeholders and citizens) within the overall approach to governance of innovative technologies. Current RRI approaches focus mainly on basic research, with the main emphasis being on stakeholder engagement, and they need to be extended to cover product and process innovation. There is a strong case for BSI to support the development of a new standards-based approach to RRI and to extend this to developing standards for responsible behaviour by regulators/policymakers and by other stakeholders and citizens.

About BSI Group

BSI (British Standards Institution) is the business standards company that equips businesses with the necessary solutions to turn standards of best practice into habits of excellence. Formed in 1901, BSI was the world's first National Standards Body and a founding member of the International Organization for Standardization (ISO). Over a century later it continues to facilitate business improvement across the globe by helping its clients drive performance, manage risk and grow sustainably through the adoption of international management systems standards, many of which BSI originated. Renowned for its marks of excellence including the consumer recognized BSI Kitemark™, BSI's influence spans multiple sectors including aerospace, construction, energy, engineering, finance, healthcare, IT and retail. With over 70,000 clients in 150 countries, BSI is an organization whose standards inspire excellence across the globe.

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Innogen Institute

The Innogen Institute (formerly the ESRC Innogen Centre) has a mission to support the delivery of innovative impacts that are profitable, safe and societally useful, building on advanced research relevant to a broad range of technologies. Its research covers: evidence-based knowledge of business models; value systems and industrial dynamics, linked to a pragmatic understanding of stakeholder perspectives and in-depth knowledge of regulatory requirements; science and innovation policy; funding models; intellectual property and standards related issues; and market-related incentives and constraints. This unique combination of cross-disciplinary insight and expertise enables the Innogen Institute to support company and policy decision-making based on a unique level of understanding of what will and will not work in the diverse sectors developing advanced innovative technologies.

Professor Joyce Tait

With an interdisciplinary background covering both natural and social sciences, Joyce has specialized in innovation–governance–stakeholder interactions in life science and related areas, including cell therapies and regenerative medicine, synthetic biology, GM technologies, drug development, stratified medicine, and biofuels, for example:

- strategic and management decision making in companies and public bodies;
- policy analysis, risk assessment and regulation;
- stakeholder attitudes, science and risk communication;
- evaluation and application of interdisciplinary research; and
- sustainable development.

Dr Geoffrey Banda

Geoff has an interdisciplinary background spanning biotechnology, quality assurance, food safety, and manufacturing, as well as professional experience in financial services covering retail, corporate and transactional banking. He is currently working on an ESRC-funded project on regenerative medicine focusing on business models, value chains and innovation ecosystems surrounding the commercialization of cell therapies in the UK.



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