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HM GOVERNMENT
GREEN PAPER - BUILDING OUR INDUSTRIAL STRATEGY

Response on behalf of the Innogen Institute, University of Edinburgh

Joyce Tait

Innogen Institute, University of Edinburgh,
Old Surgeons Hall, High School Yards,
Edinburgh EH1 1LZ

www.innogen.ac.uk
joyce.tait@ed.ac.uk



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Background

1. This response to the Green Paper builds on Innogen Institute research on the impact of government policies and regulation on innovation, and the capacity of incumbent and emerging sectors to contribute to the national economy¹. Particularly relevant is the PAGIT project (Proportionate and Adaptive Governance of Innovative Technologies)², funded by BEIS and the British Standards Institution, that is developing a framework to support better regulation of innovative technologies.
2. As the Industrial Strategy Green Paper emphasises, appropriately targeted government financial and structural support for innovative technologies plays an important role in delivering economic and societal benefits from the UK's excellence in basic science. However, **this financial and structural support will fail to deliver the expected impact unless it is accompanied by smarter, more adaptive regulatory systems that are proportionate to the benefits and risks of new technologies.**
3. The recommendations below could deliver better value for money from the investments planned in the Green Paper and could provide an 'agility dividend' for UK industries. Also, the Brexit decision has created opportunities for the UK to take a lead in becoming an internationally influential regulatory test-bed for new approaches to regulation.
4. The recommendations apply to many sectors where the UK is recognised as leading the field: life sciences in general; industrial biotechnology; synthetic biology; materials and chemicals manufacturing; regenerative medicine and cell therapies; biopharmaceuticals; personalised and stratified medicine; renewable energy and biofuels; food and drink; and agri-science. Innovation can be inhibited as a result of inappropriate choice of regulatory system for a disruptive new technology and/or failure to adapt current regulatory systems to the properties of both disruptive and incremental innovations³. The need to craft smarter regulatory systems that are able to incentivise innovation while still delivering safety, quality and efficacy is now widely recognised by governments and companies⁴.
5. This response focuses on Pillar 8, *Cultivating World Leading Sectors* (questions 31-33) and makes links where relevant to other components of the Industrial Strategy.

¹ <http://www.innogen.ac.uk/downloads/Innogen-Institute-Research-Outline.pdf>

² Proportionate and Adaptive Governance of Innovative Technologies, funded by BEIS, the British Standards Institution and the Economic and Social Research Council, <http://www.bsigroup.com/research-pagit-uk>

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

⁴ Tait, J. (2016) *Environmental Regulation of Advanced Innovative Biotechnologies: Anticipating future regulatory oversight*. Report to ShARE Group of Environment Agencies of the UK and Republic of Ireland. <http://www.sepa.org.uk/media/219333/environmental-regulation-of-advanced-innovative-biotechnologies-anticipating-future-regulatory-oversight.pdf>

PILLAR 8. CULTIVATING WORLD LEADING SECTORS

Q31 How can the Government and industry help sectors to come together to identify the opportunities for a ‘sector deal’ to address – especially where industries are fragmented or not well defined?

Q32 How can the Government ensure that ‘sector deals’ promote competition and incorporate the interests of new entrants?

Q33 How can the Government and industry collaborate to enable growth in new sectors of the future that emerge around new technologies and new business models?

1. A bioeconomy sector deal

6. The Green Paper has identified many of the important policy initiatives required to support a thriving innovation-based UK economy. However, one area that is under-emphasised in the Green Paper is the bioeconomy⁵ which contributes £36.1 Bn in GVA and 600K jobs to the UK economy, rising if combined with spending by employees to £116 Bn in GVA and 3.4 M jobs⁶. It generates this value across all UK regions and is a key growth area given that many of its contributing sectors are at the cutting edge of science and innovation. It will also be a critical factor in creating an economy that is environmentally sustainable⁷ and will be an indispensable component of the future circular (zero waste) economy⁸ (relevant to Questions 27-30). In addition to Pillar 8, the bioeconomy is relevant to all the other Pillars.
7. The life sciences are key contributors to the bioeconomy and the Green Paper includes life sciences among its early sector deals but the focus of the proposed deal will be on health related applications. This leaves out many of the major industry sectors that contribute to the bioeconomy and that are expected to benefit in a spectacular fashion from the new platform technologies emerging from life science research, including for example synthetic biology, engineering biology and gene editing⁹. The industry sectors that populate these areas are highly diverse, including industrial biotechnology, agro-biotechnology, seeds, brewing and distilling, each dominated by the business models of large companies and supported by a competitive supply chain of smaller companies. Our research has shown that, where the business models of large companies are dominant, the sector experiences mainly incremental innovation and it is difficult for small companies with disruptive

⁵ Synthetic Biology Leadership Council (2016) *Biodesign for the Bioeconomy: UK synthetic biology strategic plan*.

https://connect.innovateuk.org/documents/2826135/31405930/BioDesign+for+the+Bioeconomy+2016+DIGITAL+updated+21_03_2016.pdf/d0409f15-bad3-4f55-be03-430bc7ab4e7e

⁶ Chambers, G., Dreisin, A. and Pragnell, M. (2015) *The British bioeconomy: an assessment of the impact of the bioeconomy on the UK economy*. Capital Economics, Report to BBSRC.

(<http://www.bbsrc.ac.uk/documents/capital-economics-british-bioeconomy-report-11-june-2015/>)

⁷ OECD International Futures Project (2009) *The Bioeconomy to 2030: Designing a policy agenda*. <http://www.oecd.org/futures/long-termtechnologicalsocietalchallenges/42837897.pdf>

⁸ HoC Environmental Audit Committee (2014) *Growing a circular economy: ending the throw-away society*. Third Report of Session 2014-15.

<http://www.publications.parliament.uk/pa/cm201415/cmselect/cmenvaud/214/214.pdf>

⁹ Synthetic Biology Leadership Council (2016) *Biodesign for the Bioeconomy: UK synthetic biology strategic plan*.

https://connect.innovateuk.org/documents/2826135/31405930/BioDesign+for+the+Bioeconomy+2016+DIGITAL+updated+21_03_2016.pdf/d0409f15-bad3-4f55-be03-430bc7ab4e7e

innovation in mind to break through to independent status and to lead the development of an emerging sector with new business models and new ways of generating wealth in the economy¹⁰.

8. The innovative platform technologies (synthetic biology and gene editing) that are generating so much excitement are now opening up possibilities for new sectors that will operate in parallel with the existing sectors, serving an array of currently smaller markets with the potential to grow and to contribute to unmet societal needs and wants. These opportunities could, if given appropriate support, lead to new sectoral business models based on disruptive innovations relevant to materials manufacture, energy, food, agri-business, forestry, and other sectors. A bioeconomy deal will therefore require an explicitly cross-sectoral approach to enable a broad range of innovative business models to coexist and to learn from one another, alongside the established business models and supply chains of the incumbent sectors. Bringing so many different sectors together under a single 'deal' will require very careful management but will also create opportunities for cross-fertilisation of ideas and skills that could greatly benefit the economy in the medium term.

Recommendation 1: Develop a 'cross-sectoral deal' for the bioeconomy.

9. The bioeconomy is an area where there is great market potential, excellent UK research and industrial capability (Pillar 1), where the timing is right for a major drive, and where public money can work alongside private sector investment to make the UK a world leader.
10. A cross-sectoral deal for the bioeconomy is proposed to ensure that the UK economy is able to benefit and to compete internationally based on new scientific discoveries in synthetic biology, engineering biology and gene editing. It should cover both the incumbent bioeconomy sectors and the potentially profitable emerging sectors based on disruptive innovations. The supply chains with the most productive combinations of small and large companies could either be locally co-located or international in reach, depending on the nature of the technology and the availability of UK-based capacity and capabilities (Pillars 1 and 2).
11. The unifying basis for the proposed 'cross sectoral deal' is the platform technologies (including synthetic biology, engineering biology and gene editing) that are opening up opportunities to build emerging sectors and to support existing sectors, and to make our industries more competitive internationally. They will also contribute to climate change and other environmental targets (Pillar 7).
12. The existence of a cross-sectoral deal for the bioeconomy would enable the component sectors to benefit from their common understanding of the needs and challenges of innovating in the bioeconomy, to influence policy and other decisions from a more powerful, better organised and better informed base, and to derive greater benefit from cross sectoral synergies.

¹⁰ 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.innogen.ac.uk/reports/487>.

2. The need for more proportionate and adaptive regulatory systems

13. The Green Paper (p101) notes that, to develop a sector deal with the government would require companies to demonstrate what they could do to transform their strategic prospects, for example by “addressing a regulatory issue or deregulating”. This considerably understates the scale of the challenge, and of the benefits to be gained from addressing it, in the context of the bioeconomy (and also of other innovative sectors).
14. The regulatory systems in place for incumbent bioeconomy industry sectors have generally been built up over decades and have become rigid and non-adaptive in the face of today’s biotechnology-based innovations. Also, the more onerous, time-consuming and expensive it becomes to meet the regulatory requirements, the more a sector is dominated by the business models of very large companies and the more difficult it is for smaller companies to create new emerging sectors. These issues are increasingly well understood and there is a new emphasis by governments in many countries on the ‘innovation imperative’, including measures to ensure that regulatory systems are adaptive to the needs and properties of innovative developments and proportionate to their benefits and risks¹¹. However, beyond exhortations in strategy documents, there is no common understanding of the origins of such regulatory problems and how they can be addressed in different sectors, and there is no support for policy makers and regulators to help them to understand what will work in different sectoral circumstances.
15. The PAGIT project¹² (paras 1-3) has taken up this challenge and is developing a framework to support better decision making by policy makers and regulators in dealing with the governance of advanced innovative technologies, including those contributing to the bioeconomy. The bioeconomy is one of the sectors where the Brexit decision has created opportunities for the UK to adapt the prevailing EU regulatory systems to tailor them to the needs of innovative technologies and of UK industry sectors, contributing to the government’s aim to become a ‘test bed’ for regulatory reform. We have identified areas where existing regulatory systems could be modified and in some cases where new, more proportionate regulatory systems could be introduced, while continuing to ensure that we do not jeopardise existing trading relationships.

Recommendation 2. Create a long term leadership institution to support the creation of a world-leading regulatory and governance ecosystem for innovative industry sectors (Green Paper, p98).

16. The body of research and consultancy developed by the Innogen Institute on regulation/innovation interactions since 2002 is unique internationally. Most recently, through the PAGIT projects we have demonstrated how this research could be used to support decisions by companies, policy makers and regulators to ensure that regulatory systems are proportionate and adaptive to the needs of innovative technologies. There is a very timely opportunity for the UK to build on this body of work and to set up an institution devoted to shaping the regulatory and governance

¹¹ OECD (2015) *The Innovation Imperative: Contributing to Productivity, Growth and Well-Being*, OECD Publishing, Paris. DOI:<http://dx.doi.org/10.1787/9789264239814-en>

¹² Tait, J. and Banda, G. (2016) *Proportionate and Adaptive Governance of Innovative Technologies: the role of regulations, guidelines and standards*, British Standards Institution and BEIS, (<http://www.bsigroup.com/research-pagit-uk>)

components of the sectoral ecosystems for innovative technologies. The institution would enable industry, regulators and other stakeholders to work together within and across sectors.

17. Such an institution will require:

- the independence, authority and impartiality needed to achieve overall credibility with innovating companies and trading partners;
- involvement of industry, policy and regulatory expertise to ensure technical and financial understanding of innovative developments, in incumbent and emerging sectors and their capacity to generate future value; and
- high level leadership that can command the respect of all the players.

18. Building an authoritative, evidence-based body of expertise on what works in different sectoral contexts would play an important role in tailoring the regulatory environment for innovative technologies to maximise the benefits for industry, the economy and society. The work of the proposed institution would thus form the basis for a support system for emerging sectors and incumbent innovative businesses in the bioeconomy (p103 of the Green Paper). It could be funded through the Industrial Strategy Challenge Fund¹³ (Question 6. The value to the economy of such an investment would far outweigh its cost. To give just one example of successful regulatory adaptation, a decision by the US Food and Drugs Administration (FDA) to change the guidelines for the conduct of clinical trials on new antimicrobial drugs, brought down the cost of development of such drugs by ~50%¹⁴, contributing to the societal need for more new antimicrobial drugs to meet the challenge of antimicrobial resistance.

19. The institution's cross sectoral focus on the governance of the bioeconomy as a whole (i) would generate significant economic benefits for the UK arising from our investment in basic scientific research in life sciences in general and (ii) would contribute to the UK's ambition to take an international lead in developing regulatory systems that are fit to meet the needs of 21st century science and innovation systems.

¹³ <https://innovateuk.blog.gov.uk/2017/02/03/industrial-strategy-challenge-fund-what-is-it-and-how-is-it-being-formed/>

¹⁴ 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>.