Regulatory Horizons Council

Literature Review of Existing Papers Addressing the Theme of Innovation and Regulation

June 2022

Contents

1. Summary of Reports

A) June 2018 - Deloitte Insights: The Future of Regulation[1]

Brief Background: This study was the first in a series of Deloitte papers, this being on the future of regulation, published in June 2018.

Core arguments on good regulatory practices and ways to enable it:

- References are made in the report to ride sharing, coin offerings, Air BnB services and new ways of managing our living using of services. Quick adaptation is suggested to be key and a challenge for Government agencies.
- Policymakers have a host of reasons for regulating, but generally, they are trying to protect citizens, promote competition, or internalize externalities. Which of these reasons is most important in a given situation will impact how to answer the next critical question: What's the best regulatory model to use? A wide variety of potential approaches exist between heavy, precautionary regulation on the one end of the spectrum and little to no regulation on the other.
- Carrying out reviews of regulation every 10 years or so is one effective approach, as well as having adaptive regulation and soft law such as informal guidance and codes of conduct.

Potential weaknesses in UK and international regulatory systems:

- 53% of Asian Fintech firms cite regulations as issues. A Deloitte analysis of the 2017 US Code of Federal Regulations found that 68% of federal regulations have never been updated.
- Historical vehicle regulation in the US was referenced as an example where the regulations took a long time. Overlapping agencies, trade friction and insufficient cross border cooperation and processes were key challenges.
- Algorithms are smart, advanced and complex and widely used by industries, but can create regulatory challenges. Even the designers do not know fully how they work. Therefore, how best can government and regulators immerse themselves in and understand the matter at hand and appropriately regulate to protect the public and enable industries to function and thrive? GDPR stipulated in 2018 that more detail on algorithm use must be made available to the public.

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[1] www2.deloitte.com/us/en/insights/industry/public-sector/future-of-regulation/regulating-emerging-technology.html

B) March 2019 - NESTA Renewing Regulation: 'Anticipatory Regulation'[2]

Brief background: This report explores how regulators can adapt to secure the benefits of technological innovation while managing the risks, the approach of anticipatory regulation.

Core arguments on good regulatory practices and ways to enable innovation:

Report discusses advisory, adaptive and anticipatory models.

- Citizens' juries can be an effective way to increase public understanding of a regulatory issue, gain insight into public views and discern the circumstances in which the public may consider regulation to be important.
- Open policy making platforms can provide another opportunity for stakeholders to engage directly in the regulation drafting process.
- Report stated that the UK's pioneering role in implementing open banking is being followed by several other countries, including Australia, Canada, Germany and Mexico.

Potential weaknesses in UK or international regulatory systems:

- Erosion of sectoral boundaries. For example, online software and applications are largely outside of Ofcom's scope. Ofcom's governing framework in its original form, the 2003 Communications Act, does not include the words 'Internet', 'online' or 'web' ('broadcasting' occurs almost 500 times).
- Growing role of firms in fulfilling previously public functions. Private companies have acquired growing responsibility for some previously state-led functions. For example, social media and video sharing services increasingly play a vital role in enforcing anti-terrorism law online and potential changes to EU copyright legislation could extend their responsibilities.
- Less agile compared to US federal system. For example, while automated vehicles are underpinned by a set of national safety design principles, matters such as regulation on licensing and testing are dealt with at state level.

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[2] www.nesta.org.uk/report/renewing-regulation-anticipatory-regulation-in-an-age-of-disruption/

C) June 2019 - BEIS Regulation for the Fourth Industrial Revolution White Paper[3]

Brief background: Presented by BEIS Secretary of State Rt Hon. Greg Clark to parliament in June 2019.

Core arguments on good regulatory practices and ways to enable innovation:

- Paper sets four Grand Challenges for the UK government and wider economy to seize the opportunities presented by the Fourth Industrial Revolution:

  1. Put the UK at the forefront of the artificial intelligence and data revolution.
  2. Maximise the advantages for UK industry of the shift to clean growth.
  3. Become a world leader in shaping the future of mobility.
  4. Harness the power of innovation to help meet the needs of an ageing society.

- Refers to establishing a partnership with the World Economic Forum Centre for the Fourth Industrial Revolution in San Francisco to develop regulatory approaches for new technologies.
- Simplifying interactions with local authorities - The number of UK businesses with primary authority partnerships has grown to 73,580 as the benefits of tailored regulatory advice are more widely recognised. Local authorities also appreciate the greater clarity over where responsibility lies and the opportunity to build stronger relationships with business. There are now 188 local authorities acting as a primary authority.

D) January 2020 - BEIS Regulator Approaches to Facilitate, Support and Enable Innovation[4]

Brief background: Aims to explore the range of methods that regulators around the world are using to facilitate, support or enable innovation while fulfilling their regulatory objectives. It is based on a literature review and 35 interviews with regulators, government actors, and companies, and reviews examples across five broad types of innovation-friendly approaches, as highlighted below.

Core arguments on good regulatory practices and ways to enable innovation:

Providing regulatory advice to innovators: helping them to navigate the regulatory system ensuring that new products, services and businesses align with existing regulations and expectations, and gathering intelligence to support regulatory reform. For

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[3] www.gov.uk/government/publications/regulation-for-the-fourth-industrial-revolution
[4] www.gov.uk/government/publications/regulator-approaches-to-facilitate-support-and-enable-innovation

example, through advice centres. Examples include: MHRA Innovation Office; Ofgem's "fast, frank feedback"; SME Assist (Australia); German Federal Institute for Drugs and Medical Devices, Kick-Off Meetings, Scientific advice and pre-submission meetings; HKMA (Hong Kong) Fintech Supervisory Chatroom; and Health Canada's Device Advice – pre-clinical meetings pilot.

- **Supporting experimentation and testing of innovations**: helping innovators trail novel products to test their viability before accessing the market. Examples include regulatory sandboxes, living labs and testbeds. In 2014, the FCA launched Project Innovate to encourage innovation and promote competition through disruptive technologies. The first regulatory sandbox was established in early 2016.
- **Streamlining regulatory approvals** for innovators by providing alternative routes to authorisation and lessening initial regulatory burdens. Examples: UK-Accredited Access Collaborative Pathway (AAC); Swissmedic – Fast-track authorisation procedure; FDA De Novo classification; FDA Breakthrough Therapy Designation System; Japan – Strategy of SAKIGAKE; Hong Kong Insurance Authority Fast-Track Approval system.
- **Setting regulatory challenges** to drive innovation to facilitate learning and adaptation in response to innovation. Examples: Legal Access Challenge; Green FinTech; Challenge (FCA); Open Up Challenge (Nesta); LabCFTC Commodity Futures Trading Commission. This is one of the few approaches that actively promotes innovation rather than enabling innovation that is already happening.
- **International agreements** and regulatory harmonisation which can help firms test and bring novel products, services or business models to market quickly in several countries at the same time and reduce international barriers to innovation in regulation. Examples include Global Financial Innovation Network; Fintech Bridges; US-Japan Medical Device Harmonization by Doing (HBD); International Medical Device Regulators Forum (IMDRF); Australia-Canada-Singapore-Switzerland Consortium; EU cooperative intelligent transport systems (C-ITS) Regulation.

Potential weaknesses in UK or international regulatory systems:

- **The pacing problem**: Governments have struggled to keep pace with technological developments or know how to intervene to protect the public and create an environment that allows innovation to flourish.
- **Cultural differences** and differences in regulatory systems can be too large to develop common frameworks.
- **Non-regulatory barriers to innovation:** this can impede activities that regulators undertake, in particular, innovation testing and incentives that are challenge driven.
- **Lack of investment in robust evaluation and transparency** was found to be a predominant factor in the limited evidence on impacts of using different innovation-friendly regulatory approaches.

E) December 2020 - World Economic Forum: Agile Regulation for the 4th Industrial Revolution[5]

Brief background: Aims to be a guide providing regulators with a range of techniques they can employ to help respond in a more agile way to innovation and disruption. It builds on the World Economic Forum's 2018 White Paper, *Agile Governance: Reimagining Policy-making in the Fourth Industrial Revolution.*

Core arguments on good regulatory practices and ways to enable innovation:

- Use underline experimentation clauses to permit derogations from a regulation to enable alternative approaches to be taken, with the aim of learning how the regulation may need to adapt in the future - typically taking the form of an exemption, such as a derogation from specific requirements or from the need to seek authorisation or a permit.
- Increasingly, regulators are using hackathons and TechSprints to help address their technology needs. - Where regulators incentivise technologists to develop proposals to address a well-defined problem where no solution exists on the market. Following review by an expert panel, the best proposals are awarded an amount of research and development funding to take the idea from concept to prototype.
- Self-regulation and Co-regulation - Tacit self-regulation with little explicit state support, though its implicit role can be influential. For self-regulation initiatives, regulators may incentivise compliance by reducing the regulatory burden for businesses that choose to participate in the scheme ("earned recognition"). Benefits may include reduced reporting or inspection requirements.

Potential weaknesses in UK or international regulatory systems:

- **Regulatory challenges (and testing initiatives)** can be very costly and are able to support only a limited number of businesses. They can also be the riskiest, as they may invest in innovations that do not succeed in the market.
- **Businesses' ability to access opportunities**
  In reality, there are often many more opportunities for innovation under existing regulations than businesses realise. New or small businesses that lack experience or capacity may find it particularly challenging to navigate complex regulatory frameworks.

- **Data driven regulation**

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[5] www.weforum.org/about/agile-regulation-for-the-fourth-industrial-revolution-a-toolkit-for-regulators

In practice this relies heavily on the quality of the data and analysis that supports the prediction of compliance risk. Poor data or analysis can lead to businesses being unfairly targeted. The transparency of methods and ability to explain results are important.

F) April 2021 - OECD Paper: Agile Regulatory Governance to Harness Innovation

Brief background – This was produced at the 24th session of the Regulatory Policy Committee: 19-22 April 2021[6]

Core arguments on good regulatory practices and ways to enable innovation:

- In light of the regulatory challenges raised by innovation, governments need to undertake a paradigm shift in their regulatory policy processes, whereby the traditional "regulate and forget" mindset must give way to "adapt-and-learn" approaches, using interim and ex-post reviews.
- Strengthen co-ordination and collaboration across policymaking departments and regulatory agencies as well as between national and sub-national levels of government.
- Credible sanctions needed for soft law non-compliance or under performance.

Potential weaknesses in UK or international regulatory systems:

- Enforcement across borders can be challenging on liabilities or in accidents. Depending on legal frameworks and enforcement approaches, governments can end up either cracking down indiscriminately on innovations that do not fit previously existing categories, or powerless to respond to emerging risks – or both at the same time. COVID-19 has magnified challenges and need for agility and swift implementation of regulation.
- How can international regulatory co-operation support domestic regulatory approaches to phenomena that know no borders? - institutional and transboundary challenges arise.
- Acknowledged that there can be a pacing problem from forming regulations to the point of implementation. New forms of regulatory intervention may also be needed to address potential market failures in some digital markets.

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[6] www.oecd.org/mcm/Recommendation-for-Agile-Regulatory-Governance-to-Harness-Innovation.pdf

G) June 2021 - Taskforce on Innovation, Growth and Regulatory Reform Report[7]

Brief background: The Prime Minister asked for the formation of a Taskforce on Innovation, Growth and Regulatory Reform (TIGRR) to consider how the UK can best take advantage of its new-found regulatory and trade freedoms outside the EU. The report was published in June 2021.

Much of the best practice found by the report was from the devolved administrations – Scotland, Wales, Northern Ireland, and the report aims to support the broader levelling up agenda. The report says regulations should focus on outcomes rather than inputs and end product, not the process. Simple, agile and proportionate regulatory systems are called for now we are no longer in the EU orbit.

Core arguments on good regulatory practices and ways to enable innovation:

- Reimpose 1 in 2 out regulatory offset principal duty on all Govt depts. The Red Tape Challenge was launched in 2011 to remove unnecessary and burdensome regulation. In 2014, the Government announced that the project had saved businesses £10 billion over four years. Many of the Challenge's proposals were included in the Deregulation Act 2015.
- Give the Regulatory Reform Committee the power to scrutinise regulators and their proposals. Bolster its resources with seconded experts.
- Produce a simple annual innovation scorecard to assess departments and regulators on the markets they are responsible for.
- Regulators should introduce Scaleboxes - which provide additional supervisory support to companies in their growth phase.

Potential weaknesses in UK or international regulatory systems:

- A lack of provision of adequate capital for scale-up of ventures is highlighted as a historic UK weakness. The UK finance sector has been limited in the capital it can inject into innovative companies by the way the pensions and insurance sectors are currently regulated.
- GDPR is out of date and needs to be revised for AI and growth sectors if we want to enable innovation in the UK.
- Net Zero smart energy needs massive change in regulatory frameworks. This report says it should be the start of a process through which government departments review all aspects of EU regulation (especially those rules which the UK voted against in the Council of Ministers) to assess which to remove, reform or retain.

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[7] Taskforce on Innovation, Growth and Regulatory Reform Report

- Retained EU law: The European Union (Withdrawal) Act 2018 retained thousands of EU regulations forming a body of "retained EU law" in UK domestic law to ensure the statute book remained functional.

H) July 2021 - BEIS UK Innovation Strategy: Leading the Future by Creating it[8]

Brief Background: The UK Innovation Strategy sets out the government's vision to make the UK a global hub for innovation by 2035. The Prime Minister has announced the UK's intention to be a science superpower by 2030.

Core arguments on good regulatory practices and ways to enable innovation:

- Innovators operate in a complex environment of legal, voluntary and regulatory frameworks. A well-designed regulation system provides certainty to reduce investment risk and the clarity needed to make markets function effectively. It can encourage innovation, create consumer confidence, steer development of new products, and enable the rapid but safe adoption of new and disruptive technologies.
- The UK government's approach to regulation has evolved over the past ten years. Initiatives such as the Red Tape Challenge and the 'One In, Two Out' policy sought to reduce regulatory burdens on firms. Building on this, the 2019 'Regulation for the Fourth Industrial Revolution' white paper set out how regulation can actively support and promote the development and adoption of innovations. This approach can be seen in our work with regulators through the Regulators' Pioneer Fund, assisting and enabling experimentation through the use of regulatory sandboxes and cutting-edge healthcare solutions.
- The Strategy committed to ;

  Commissioning the Regulatory Horizons Council to consider how best to support innovation through regulation

  Maintaining global leadership in regulation through regulatory diplomacy, and extend the reach of the 'Agile Nations' network by engaging more countries.

  Publishing a joint Action Plan on Standards for the Fourth Industrial Revolution with the British Standards Institution (BSI), the National Physical Laboratory (NPL) and the UK Accreditation Service (UKAS). This plan will champion an agile approach to standardisation to respond to fast-paced

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[8] www.gov.uk/government/publications/uk-innovation-strategy-leading-the-future-by-creating-it

technological change and foster synergies between standardisation, policy making and strategic research work that are needed to underpin innovation across sectors.

Publishing the UK Measurement Strategy will be published which will outline how the UK will capitalise on its world-leading status to provide the measurement infrastructure that the UK needs to innovate and be safer, healthier, greener and more prosperous.

Potential weaknesses in UK or international regulatory systems:

- The precautionary principle can be interpreted in ways that can produce more harm than good. In some cases, the precautionary principle has become a policy of blocking all potential harms, even a possibility of harm, without a balanced analysis of likely benefits. One example is Genetically Modified (GM) crops, where the EU relied on a strict interpretation of the precautionary principle which resulted in the absence of any significant adoption of GM crops in the EU and the departure of European companies working on GM technologies to the USA and other countries. This was despite the potential these technologies have in contributing to our work to tackle climate change.

I) July 2021 - BEIS Standards for the Fourth Industrial Revolution[9]

Brief background: This joint action plan sets out how government, the British Standards Institution, the National Physical Laboratory, and United Kingdom Accreditation Service will work together to unlock the full potential of voluntary standards to support innovation and enable its swift and safe commercialisation.

Core arguments on good regulatory practices and ways to enable innovation:

- Strengthen strategic coordination between government and our National Quality Infrastructure (NQI) on future priorities for standardisation.
- Office for Product Safety and Standards at BEIS will create a cross-Government Standards Network to enable sharing of experience and best practice between officials. In the longer-term members of the Network should be empowered to act as champions to raise the profile of standards within their departments.
- The British Standards Association (BSI) has developed BSI flex - faster development times, works through iterations of the standard and the scope and pace are market driven. This was used when developing guidance for safe working

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[9] www.gov.uk/government/publications/standards-for-the-fourth-industrial-revolution-action-plan/standards-for-the-fourth-industrial-revolution-hmg-nqi-action-plan-to-unlock-the-value-of-standards-for-innovation-html

during Covid-19 and proved very flexible and agile. This report recognises that SMEs often cannot sustain levels of engagement and effective participation with regulators.

- The Agile Nations intergovernmental network - which the UK has recently established with six other countries, provides a forum for focused and ambitious engagement on the potential role of the NQI as part of wider agile approaches to regulating new technologies.[10]

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[10] www.weforum.org/press/2020/12/nations-sign-first-agreement-to-unlock-potential-of-emerging-tech/

2. Key Common Themes in the Reports Reviewed

In the process of summarising each of these reports on the regulation of technological innovation, the RHC found a strong recognition that the UK is very highly rated for its regulatory system, standards and consultation with both industry and the public.

It also found the below to be the most frequently cited suggestions for improving the UK's regulation of innovation:

1. More "one-stop shops" or innovation hubs.
2. Greater direct delegation of powers and discretion to regulators.
3. Testing sandboxes and data driven regulation. Seek to put in place more adaptive regulation, easier and quicker to amend.
4. Continued engagement with stakeholders, SME's and innovators through the processes of design and implementation of intended regulation and on the desired outcomes.
5. Soft law approaches – codes of conduct, self-regulation - but some risks acknowledged around potential for under performance and lack of compliance. Useful though for Tech and early-stage innovations.
6. Using sunset clauses and defined points of review to help identify when and how existing regulation may need to be revisited to achieve their existing or new goals in a changing environment.
7. Need to undo/ release from historical EU tied laws.

3. Key Areas of Focus in Reports Reviewed

Taskforce on Innovation, Growth and Regulatory Reform Report

- Suggests the UK could replace the EU model with a Proportionality Principle. Regulations based on outcomes rather than prioritising compliance.
- Give Regulatory Reform Committee power to scrutinise regulators and their proposals. Bolster its resources with seconded experts.
- Produce a simple annual innovation scorecard to assess departments and regulators on the markets they are responsible for.

OECD Paper: Agile Regulatory Governance to Harness Innovation

- Emphasises need to strengthen co-ordination and collaboration across policy-making departments and regulatory agencies as well as between national and sub-national levels of government.
- In light of the regulatory challenges raised by innovation, governments need to undertake a paradigm shift in their regulatory policy processes

Standards for the Fourth Industrial Revolution

- Office for Product Safety and Standards (OPSS) at BEIS will create a cross-Government Standards Network to enable sharing of experience and best practice between officials. Longer-term, members of the Network should be empowered to act as champions to raise the profile of standards within their departments.
- Strengthen strategic coordination between government and our National Quality Infrastructure (NQI) on future priorities for standardisation.
- UK needs to be first mover in developing the new standards required – as our accreditation and standard setters are acknowledged as world leaders – led by our NQI.

UK Innovation Strategy: Leading the Future by Creating it

- Recognition that this sits alongside important work being taken forward by the devolved administrations, including Northern Ireland's Decade of Innovation, 'a 10X Economy' and Scotland's Innovation Action Plan.
- Says that Government intends to use the weight of public sector procurement to drive innovation. This will be aided by ongoing government procurement reform post-EU Exit.
- Government will consult on potential value of and options for a UK capability in digital twinning and wider 'cyber-physical infrastructure'.

- Set up the Government Office for Technology Transfer to support public sector organisations in identifying wider uses for their innovations.

NESTA - Renewing Regulation: 'Anticipatory Regulation'

- Looks at regulation and innovation with some reference to the 2008 financial crisis and culture change that followed.
- Nesta led the Open Up Challenge, creating financial incentives for third parties to develop useful innovations that build on open banking functionality, rewarding the most impactful.
- Mentions growing role of private firms in fulfilling previously public/state-led functions – for example: social media and video sharing services increasingly play a vital role in enforcing anti-terrorism law online.
- Says that UK is less agile compared to US federal system – For example, Automated vehicles. While underpinned by a set of national safety design principles, matters such as regulation on licensing and testing dealt with at state level in US.

World Economic Forum - Agile Regulation for the 4th Industrial Revolution

- Risk-based enforcement - Regulators should target this according to the likelihood and impact of non-compliance by different businesses at a given point in time.
- In the same way, enforcement actions should be designed to reduce the risk of non-compliance.
- Businesses' ability to access opportunities. Report says that in reality there are often many more opportunities for innovation under existing regulations than businesses realise. New or small businesses that lack experience or capacity can find it particularly challenging to navigate complex regulatory frameworks.

BEIS - Regulator Approaches to Facilitate, Support and Enable Innovation

- Advocates for developing approaches that are explicitly "innovation-enabling," to increase business trust and facilitate open and transparent relationships with businesses.
- Did not find any evidence for increased consumer trust in new products, services and business models or greater public engagement through the initiatives recommended, but recognises further research required here.