REGULATORY HORIZONS COUNCIL

‘Closing the Gap’

Getting from Principles to Practices for Innovation Friendly Regulation

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Foreword from the Secretary of State

The UK has undergone exceptional challenge over the last few years. As we emerge from the pandemic and continue to seize opportunities arising from EU Exit, we must build on this country’s innovative foundations. This will create a robust economy that is fit for future generations.

Unlocking innovation is an essential element in tackling some of the largest challenges the world faces today. To address this challenge, my department published the Innovation Strategy, and as part of that I commissioned the Regulatory Horizons Council to provide its view on how best to enable innovation through regulation. It is now time we think boldly about how we regulate and this report from the Regulatory Horizons Council is very timely as the government introduces its new approach to regulation post Brexit.

Regulation is a key enabler for technological innovation. As we deliver our ambitions by designing, implementing, and evaluating our regulatory interventions, it is important to consider how these principles that govern innovation are adopted and how they work in practice. The Council raise the important point that innovation does not occur in isolation, and a joint effort from government, regulators and innovators can foster an environment to achieve the UK’s ambitions.

I am very grateful to the Council for playing its part, lending its expertise, and contributing its own analysis and I look forward to responding to the report and more broadly considering the next steps towards seizing this moment to make the UK a global science superpower.

RT HON KWASI KWARTENG MP

Secretary of State for Business, Energy, and Industrial Strategy

Foreword from Chair of Rolls-Royce

At Rolls-Royce, we believe in the positive, transforming potential of technology. Whether that is creating advanced propulsion technologies that can accelerate the decarbonisation of commercial aviation, new innovations for application in defence, cutting-edge solutions for the space sector, or small modular nuclear reactors that can help meet the future zero carbon energy needs of the UK and elsewhere. A regulatory environment that is supportive of innovation is vital to ensuring technological advances. These can generate economic value and ensure that the UK retains its place as a global innovation leader, across multiple sectors, in the face of intense global competition.

At its best, regulation is a key enabler for new and emerging technologies rather than a prohibitive barrier to progress. It can also form part of a virtuous circle: innovation creates valuable intellectual property, which can be nurtured by a regulatory environment which uses that IP to lead in the setting of global regulations, reinforcing a country’s first mover advantage. Regulation can enable and boost market confidence to invest significantly in products and services at an early stage of maturity. Regulation that proportionately accounts for the risks and benefits associated with new technologies can also help build public confidence and acceptability, which is an important prerequisite for widespread adoption.

Recognising there have been numerous attempts to establish a set of principles for regulating new and emerging technologies, I welcome this practical report from the Regulatory Horizons Council that aims to go beyond principles. The report addresses some of the gaps that exist between regulatory principles and practices through six focal points and accompanying recommendations, and outlines pathways and case studies for how regulators, policymakers and innovators can come together to close the gap. We look forward to business working with Government to help shape our regulatory future.

Anita Frew, Chair, Rolls-Royce.

Executive summary

Innovation is about finding new and better ways of doing things. It has been critical to the success of humanity and is vital for our continued, sustainable prosperity. However, innovation is fragile. It relies on a series of coincidences and connections that enable ideas to become a reality. The success of technological innovation, the extent to which it creates societal, economic, or environmental benefits, is highly sensitive to the circumstances and context into which it is born.

The role of the Regulatory Horizons Council is to highlight areas in which regulatory reform may unlock potential benefits in technological innovation. Regulation is an important element in determining whether and to what extent technological innovation delivers value and in determining to whom those benefits accrue.

Regulation can be supportive of innovation. Markets are places where buyers can meet sellers and where transactions take place. These interchanges are important enablers of innovation, and this inherently competitive process incentivises innovation and helps to ensure its benefits are enjoyed by consumers. Regulation plays an important role in creating markets whilst promoting and protecting the competitive process. This is most obviously done by competition authorities and economic regulators. Other regulators also have an important role to play in creating rules that set out or influence the scope of markets and the nature of competition, and it is important that they are mindful of their impact.

Importantly, regulation can also contribute to building public trust in the uses of innovative technologies. Knowing that a new technology must conform to certain standards, have specific use cases, or that redress must be provided if something goes wrong, can be crucial in enabling public confidence in taking up and using a new technology. Linked to this, regulation that addresses potential public concerns in a proportionate, clear, and predictable way can be important in enabling investment.

But we also know that the design and implementation of regulation can *unduly* restrict or hinder innovative new technology.

There is no shortage of principles to which regulators and policymakers are told ‘good regulation’ should conform. We have looked at many and have found they contain themes that are supportive of innovation, including the importance of collaboration, being proportionate and adaptable, being outcomes-focused and future-facing. Yet, we continue to see evidence of regulatory barriers to innovation, either in terms of regulatory design or its implementation.

It is important that we close the gap between these principles of good regulation and regulatory practice as it impacts new technologies.

Regulators and policymakers appreciate the impact that their work has on innovation. Their work is complex, they face competing priorities and have finite resources. In this report we aim to provide practical help to enable regulators and policymakers to be more supportive of technological innovation. Through our discussions with innovators, academics, and commentators, as well as with regulators and policymakers we have identified six 'focal points' for those involved in regulatory design and implementation and provide case studies in support of each. We believe focus is needed on:

Focal Point 1: Regulation should adopt a proportionate approach to risks and benefits

- This starts with a nuanced consideration of risk. This includes the risk that new technology might result in harm, the benefits it might create, and the risk that regulation may result in those benefits not being realised. It also requires a look across the full range of regulatory tools and proper consideration of options that might not involve regulatory intervention beyond the maintenance of a 'watching brief'.

Focal Point 2: Regulation and innovation should embrace ethics and public engagement

- This asks regulators and policymakers to acknowledge that they make value judgements in their work and recommends that they be explicit about the framework they use and factors they consider in reaching those judgements. This improves transparency and predictability, and enables others to challenge those frameworks, for example where they are based on assumptions that no longer hold true.

- Regulators need to guard against being unduly influenced by arguments against change. Including barriers to entry coming from existing technologies and business models with a vested interest in the status quo and good political connections. A more open, accessible, inclusive engagement process will help to ensure that regulatory design and decision-making is not unduly influenced (consciously or unconsciously) by old technologies, to the detriment of innovation. This requires regulators and policymakers to think carefully about how they conduct public engagement. They must recognise that who, how and when they engage will have a significant impact on the conclusions they draw from public engagement.

Focal Point 3: Regulation should take account of commercial considerations and the need to attract investment

- This asks regulators and policymakers to understand not only the uses of new technology but also how it will secure investment and create a proposition that is

commercially viable. Only with this understanding, which needs to be grounded in business reality rather than theory, can regulators and policymakers properly take account of the impact they have on innovators.

Focal Point 4: Regulatory design and implementation should consider alternative forms of regulation

- The ability of regulation and regulators to adapt to change is critical in enabling innovation. We ask regulators and policymakers to give greater consideration to alternative forms of regulation, such as standards, guidance, and best practice rather than rushing to regulate using tools such as legislation. These tools need to be used with care but well. Often legislation and alternative forms of regulation are considered as independent actions, but interplay between these two options provides flexibility and can be a powerful enabler of innovation. We are also supportive of the use of 'sandboxes' and 'scaleboxes', which UK regulators have pioneered, and which could be used more.

Focal Point 5: Regulation needs to get the timing right

- There are risks in regulating too early because it could unnecessarily preclude new technologies. There are risks in regulating too late, because investment could become stranded or public trust might have been lost, due to the risk of harm having already occurred. Regulation can also just become outdated. So, we ask regulators and policymakers to be mindful of this 'pacing problem'. Horizon scanning, scenario testing, the use of adaptable regulatory tools, and post-implementation reviews are all important here.

Focal Point 6: Regulators should foster a culture of openness and a growth mindset

- Regulation is designed and implemented by people, not faceless institutions. The culture and mindset of those developing and implementing regulations therefore needs to be a focal point in itself. Regulators need to be able to access skills and experience outside their own institutions, they need to be open to collaboration and co-creation. The existence of a 'fixed mindset', where people feel good when they are doing what they know and are being rewarded for knowing the 'right' answer, can militate against the sort of openness and willingness to learn and adapt that is essential for innovation. There is a link here with our recommendation on getting the timing right – the best can be the enemy of the good and a timely, but 'imperfect' regulatory decision might be the best one, especially if a mechanism to learn and adapt is put in place.

- Regulation is not all about regulators and policymakers. Regulation is a process of interaction between regulators and those they regulate (and wider society). We will not achieve a regulatory environment that is more enabling of innovation only by seeking change on the part of regulators and policymakers. It is important that innovators play their part too. They can do this by seeking themselves to

understand and adapt to potential public concerns, and adopting responsible innovation approaches, such as those set out by the British Standards Institution and the OECD in respect of neurotechnology. This in turn should provide regulators and policymakers with confidence that innovators are taking wider considerations into account, making dialogue more constructive and potentially leading to less direct regulatory intervention.

In summary our recommendations are:

Regulators and policymakers should:

- always include cost-benefit analysis and regulatory impact assessments when evaluating the impacts on innovation. This should be taken into account in deciding whether and how to regulate. We highlight types of regulatory interventions that are likely to have an impact technological innovation and recommend that alternative approaches be considered. (Recommendation 3)
- develop tools for broader and deeper stakeholder and public engagement and do more to share learning and best practice in the use of these tools. This could involve joint work across regulators and with experts in the field. (Recommendation 5)
- make more use of collaboration and co-creation and do more to share experiences, which a view to develop best practice in the use of these tools. (Recommendation 12)
- make more use of adaptive regulatory tools, such as 'sandboxes' and 'scaleboxes', and do more to share learning and best practice in the use of these tools. (Recommendation 9)
- undertake horizon scanning and share the results of this work across other regulators and policymakers. Including the use of existing horizon scanning work, for example, by the Government Office for Science. (Recommendation 10)
- develop and share expertise in areas that are critical for technological innovation, such as artificial intelligence, and data science. This could be done by making more or better use of existing bodies or, if appropriate bodies do not exist, creating a panel that could be used across regulators and policymakers. (Recommendation 11)
- encourage innovators explicitly to adopt 'responsible innovation' approaches and take these into account in the design and implementation of regulation. (Recommendation 6)
- consider making explicit statements about the ethical frameworks that guide their decision-making, especially with respect to decisions in sensitive or contentious areas. (Recommendation 4)
- consider establishing an investor panel, including investors in disruptive technologies, which can then be used as a sounding board in the development and implementation of regulation. (Recommendation 7)

- work with appropriate bodies (such as the newly-formed Institute of Regulation to design and provide training resources and courses for regulatory professionals on best practice on regulation and innovation. (Recommendation 2).

The government should:

- deliver its 'renewed regulatory framework' as set out in the 'Benefits of Brexit' publication incorporating the four overarching themes of regulation that support innovation as outlined in this report. (Recommendation 1)
- maintain its commitment to the introduction of regulation only when necessary and consider alternatives to regulation and to signpost best practice. (Recommendation 8)
- design a regulatory pathway that takes account of how regulation has been developed including the extent to which regulation has been developed in a way that builds in effective collaboration or co-creation. (Recommendation 12)
- develop and implement guidance for regulators and policymakers to assess the impact of regulation on innovation as part of cost-benefit analysis and regulatory impact assessments. (Recommendation 3)
- share horizon scanning outputs on new and emerging technologies with regulators. (Recommendation 10)

Parliamentarians and civil society groups and other relevant bodies should:

- hold regulators and policymakers to account for how they develop and implement regulation, including how they engage with and involve the public. (Recommendation 5)

Innovators should:

- explicitly adopt a 'responsible innovation' approach, such as the BSI's responsible innovation standard and as outlined in the OECD recommendations concerning the governance of neurotechnology. (Recommendation 6)

1. Background

The Regulatory Horizons Council is an independent expert committee, supported by a team of civil servants, established by the Department for Business, Energy, and Industrial Strategy (BEIS). A commitment from the White Paper on Regulation for the Fourth Industrial Revolution[1], it provides the Government with impartial, expert advice on regulatory reform to support the rapid and safe introduction of technological innovations with high potential benefit for the UK economy and society.

Scope

In the Innovation Strategy, the UK Government commissioned the Regulatory Horizons Council:

"… to consider how best to support innovation through regulation, including looking at whether there are a set of high-level guiding principles for regulation that may apply broadly to any sector of innovation. We will ask the Council to work with regulators, industry, government, and other stakeholders as they see fit. They will develop and test their recommendations, source tangible case studies of pro-innovation regulation in action, and ultimately present their conclusions to government."

The Council initially considered the merits of developing a set of high level guiding regulatory principles for innovation. On review, however, it was recognised that there have been many attempts by Government/non-Government actors to distil a set of principles/codes either for 'good' regulation broadly (e.g., Regulators Code) or more specifically regulatory principles for regulating technological innovation (e.g., Deloitte, Nesta, OECD). In light of this, it was felt that the most relevant - and indeed urgent - question to address was '**What are the main gaps between regulatory principles and practice in relation to innovation and how can they best be closed**? For example, in speaking to regulators, policymakers, and other stakeholders, most people supported the basic principles of being 'outcome focused' and aiming to be 'proportionate' and would see themselves as acting in line with these principles. There are, however, real challenges to achieving these aims.

Therefore, our report focuses on:

- Firstly, reflecting on the existing literature on regulatory principles for innovation and briefly drawing out the main themes that come up time and time again.

[1] www.gov.uk/government/publications/regulation-for-the-fourth-industrial-revolution

- Secondly, highlighting what we think the key gaps are between regulatory practice and these principles.

Our intention is to provide a set of prompts primarily for regulators and policymakers, but also other stakeholders to reflect on what they do and how they do it, and to challenge themselves to be more conscious of their impact on innovation.

Our approach

To achieve the above, we:

- Conducted **a survey** (Annex A)[2] **with regulators** to explore how they see themselves currently supporting innovation, as well some of the practical barriers to providing this support.
- Carried out a **small-scale literature review** (Annex B)[3] using a snowball sampling approach[4] focusing on literature broadly addressing the theme of innovation and regulation.
- Had **discussions** with the Regulators' Innovation Network[5], international counterparts in the Agile Nations[6] and a variety of key thinkers on regulation and innovation[7]**.**
- **Reflected on the Council's collective experiences in** producing our four published studies on fusion energy, drones, medical devices and genetic technologies, and our ongoing work on neurotechnology, artificial intelligence as a medical device, and hydrogen in maritime.

What we hope to achieve

This report highlights several case studies to bring to life how regulatory principles can enable innovation in practice. In this way we show how some of the gaps we identify between the aspiration for regulation that enables innovation, and the reality can be closed. We hope to prompt regulators and policymakers to reach out to others. We also

[2] Annex A is published as separate document on gov.uk

[3] Annex B is published as separate document on gov.uk

[4] https://methods.sagepub.com/foundations/snowball-sampling

[5] The Regulators' Innovation Network (RIN) is an informal group of UK regulators with a keen interest in innovation and technology. It provides a space to share best practice and learn from each other with the objective of mainstreaming proven regulatory approaches and fostering a culture of experimentation and collaboration. (add a link to the RIN here?)

[6] www.gov.uk/government/groups/agile-nations#what-is-the-agile-nations

[7] List is published at the end of this report.

want to provide innovators or civil society groups with useful prompts for discussion with regulators and policymakers, including holding them to account for following good practice. It could also help innovators and civil society groups to better understand the concerns and approaches of regulators and policymakers. A better-informed dialogue can only improve the regulatory process to the benefit of all.

2. Introduction

Why innovation matters

There are multiple definitions of innovation[8,9] but at its simplest level, innovation is about finding new and better ways of doing things.

Innovation is a continuous and iterative process, where ideas become practical reality, and real-world challenges and opportunities spark new ideas. At its pinnacle, innovation is the process by which things we did not know could exist, let alone were needed, become things we cannot live without. The lifesaving impact of vaccines, diagnostics, and treatments in response to the COVID-19 pandemic has recently showcased why innovation matters.

Innovation is the engine of increasing prosperity, understood not only as increasing financial wealth, but also environmental sustainability, and social capital and wellbeing. It is not always and everywhere a good thing, but generally, 'good' innovation vastly outweighs 'bad' because people select innovations that bring benefits[10].

For all its power, innovation can be fragile. The process of discovery, invention, development, and adoption is subject to many influences. Some of these will be genuinely random events, but some are more systemic in nature. It is therefore possible to create an environment that is more conducive to innovation, even though *exactly* which policies *best* promote innovation may remain unclear. The UK Government's Innovation Strategy aims to create such an environment in the UK. It recognises that innovation, 'is an essential part of the UK's future prosperity and key to achieving UK objectives to be a force for good on global challenges around climate, biodiversity, prosperity and security'.

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8 A common definition of innovation is from OECD which defines innovation as: "An innovation is a new or improved product or process (or combination thereof) that differs significantly from the unit's previous products or processes and that has been made available to potential users (product) or brought into use by the unit (process)." OECD (2018) 'Oslo Manual'

9 In the Innovation Strategy, the UK Government defines innovation as: "the creation and application of new knowledge to improve the world". - www.gov.uk/government/publications/uk-innovation-strategy- leading-the-future-by-creating-it

10 Recognising that there is a distinction between 'good' and 'bad' innovation, there have been previous attempts to suggest a framework or criteria that help to distinguish them. But this is incredibly complex with future technological innovations where there is much uncertainty on their use, and the possible winners and losers.
www.sciencedirect.com/science/article/pii/S0048733313000930 /
www.nesta.org.uk/blog/good-and-bad-innovation-what-kind-of-theory-and-practice-do-we-need-to-distinguish-them/

Why regulation matters for innovation

Regulation does not exist to promote innovation but is a critical part of the landscape that influences innovation[11]. Most regulation has its genesis in a desire to prevent serious harm to people or to things people care about, such as the environment. But regulation or the way in which regulation is created, communicated, and implemented can impact innovation.

Regulation can be an impediment to innovation

How?	Examples
The regulatory impediment towards innovation can be explicit.	The choice by Indian authorities to **ban e-cigarettes**[12]
The regulatory impediment towards innovation can be implicit, where it denies access to something that is essential for its success.	The **denial of spectrum to cellular services** meant their development was severely delayed, but as the counter-factual is not evident, it is hard to prove this.
In some cases, innovations will not be adopted because regulation has adversely affected the costs and benefits. This could be a result of the *substance* of the regulation to which a new product or service is required to conform.	The prohibiting of **incandescent lightbulbs** was influenced by manufacturers of compact fluorescent bulbs. This change benefited these manufacturers but made it harder for LED manufacturers and delayed the introduction of LEDs[13]. **Genetically modified organisms** were never banned in the European Union, but the process and uncertainty around their regulation led to some companies such as BASF simply abandoning innovations that had been in-development[14].
Regulatory uncertainty - investors can be put off when regulation is expected but the timing and scope/shape has not been determined. This uncertainty puts risks in business planning and can impede on investment.	**Fusion energy technology** has reached a point, where further development would be a financial and resource risk without greater clarity over the regulatory approach. Global growth in **drone** delivery services has been slower than anticipated, largely due to regulatory uncertainty on the shape of regulation of drones in urban areas, shared airspace, and near airports and helipads.[15]

[11] A useful economic analysis of the impact of regulation on innovation can be found in Blind, K (2012) The Impact of Regulation on Innovation, Nesta Working Paper 12/02, available at: www.nesta.org.uk/report/the-impact-of-regulation-on-innovation/

[12] www.theguardian.com/society/2019/sep/18/india-bans-e-cigarettes-as-global-vaping-backlash-grows

[13] www.aei.org/carpe-diem/crony-capitalism-how-private-industry-used-government-force-to-kill-the-traditional-light-bulb-for-higher-profits/

[14] https://onlinelibrary.wiley.com/doi/full/10.1002/fes3.100

[15] www.clydeco.com/en/insights/2021/11/regulatory-uncertainty-main-obstacle-to-developmen

Regulation can stimulate innovation

How?	Examples
By creating markets and promoting and protecting competition, regulation plays an important role in enabling new entry and disruption by innovators and fostering incentives for innovation.	For example, electric vehicle charging competition on motorways, enabled drivers to have greater choice of charge points. This made way for greater choice, investment, and competition on prices for electric vehicle drivers.[16]
Regulation can also help to create the conditions in which people feel confident to take up and use technological innovations.	**Product safety standards** can help customers be confident that a new product is safe to use, helping to create demand for the product and the conditions for its economic viability. **For example, this may prove to be important in the roll out of autonomous vehicles.**[17]
By creating constraints, such as new standards, regulation can create an incentive or imperative to find new ways of doing things, improving current products, or creating entirely new ones.	Tightening emissions standards for cars, for example, has spurred **manufacturers to develop new engine technologies**. Regulation of health and safety in the workplace has stimulated the **developments of robots** that can work safely in environments that are hazardous for humans.[18]
Regulators create specific incentives for innovation.	Economic regulators, such as Ofgem and Ofwat, have sought to stimulate innovation in the firms they regulate by **setting up 'innovation funds'** for which those firms can compete.[19,20]
Clarity on a regulatory regime can be key to unlocking the next stage in technological development and investment	The establishment of European **standards for the use of 2G mobile technology resulted in opportunities grasped by companies such as Nokia and Ericsson**.[21]

[16] www.gov.uk/government/news/cma-to-open-up-electric-vehicle-charging-competition-on-motorways

[17] www.lawcom.gov.uk/project/automated-vehicles/

[18] www.gov.uk/government/news/teaching-a-new-dog-nuclear-tricks

[19] For the Ofwat fund, see: www.ofwat.gov.uk/regulated-companies/innovation-in-the-water-sector/water-innovation-competitions/

[20] For the Ofgem fund, see: www.ofgem.gov.uk/energy-policy-and-regulation/policy-and-regulatory-programmes/network-price-controls-2021-2028-riio-2/network-price-controls-2021-2028-riio-2-riio-2-network-innovation-funding/strategic-innovation-fund-sif

[21] https://arxiv.org/pdf/cs/0109100

3. Existing Principles for Better Regulation

There is no shortage of principles that relate to how regulation should be designed and implemented, domestically and internationally. The following tables briefly summarise publications that highlight a) existing principles for better regulation/regulators as a whole and b) principles for regulation and innovation. The list is not meant to be exhaustive.

General Principles for Better Regulation

Source	Principles
1998 - The Better Regulation Task Force publishes a set of basic principles of Better Regulation later endorsed by the government[22].	**Proportionality:** Regulators should only intervene when necessary. Remedies should be appropriate to the risk posed, and costs identified and minimised. **Accountability**: Regulators must be able to justify decisions and be subject to public scrutiny. **Consistency:** Government rules and standards must be joined up and implemented fairly. **Transparency:** Regulators should be open and keep regulations simple and user-friendly. **Targeting:** Regulation should be focused on the problem and minimise side effects.
2006 - The Legislative and Regulatory Reform Act 2006	Regulatory activities should be carried out in a way which is **transparent, accountable, proportionate and consistent.** Regulatory activities should be **targeted** only at cases in which action is needed.
2014 - The 2006 legislation cited above also brought into effect the Regulators' Code on 6th April 2014.[23]	Regulators should carry out their activities in a way that supports those they **regulate to comply and grow**. Regulators should provide simple and straightforward ways to engage with those they regulate and hear their views. Regulators should **base their regulatory activities on risk**.

[22] To note these principles are not enshrined in legislation https://webarchive.nationalarchives.gov.uk/ukgwa/20100407173247/http:/archive.cabinetoffice.gov.uk/brc/upload/assets/www.brc.gov.uk/principlesleaflet.pdf

[23] www.gov.uk/government/publications/regulators-code

Source	Principles
	Regulators should **share information** about compliance and risk. Regulators should ensure **clear information, guidance and advice is available to help those they regulate** meet their responsibilities to comply. Regulators should ensure that their **approach to their regulatory activities is transparent**.
2015 - The Deregulation Act 2015 (Growth Duty)[24]	This required that specified regulators[25] consider the potential **impacts of their activities and their decisions on economic growth.** The guidance clarifies how regulators can incorporate the growth duty. This can be done by developing an understanding of the business environment and those they regulate, including the impact of their activities.
2021 – National Audit Office Principles published a framework for policymakers and regulators overseeing any given market, sector or regulatory issue [26]	**Design:** These principles are to help translate the policy intent and purpose of regulation into the design of an overall regulatory framework. **Analyse:** These principles are to help regulators and policymakers analyse the market or issue being regulated and identify and assess where problems are occurring that may require intervention. **Intervene:** Where regulators identify problems, these principles are to help them understand what impact they might have, prioritise actions, and consider how best to respond. **Learn:** These principles are to help regulators and policymakers maximise their effectiveness in future by learning from experience and working in a joined-up way with other organisations.
2022 – Reforming the Framework for Better Regulation[27]	**A sovereign approach:** The UK will use its new freedoms to follow a distinctive approach based on UK law, protected by independent UK regulators and designed to strengthen UK markets. **Leading from the front:** The UK will focus on the future, shaping and supporting the development of new technologies and creating new markets. The UK will use its new freedom to act quickly and nimbly and will pursue high - quality regulation because it leads to better markets. **Proportionality:** Where markets achieve the best outcomes, the UK will let them move freely and dynamically. The UK will pursue non-regulatory options

[24] www.gov.uk/government/publications/growth-duty

[25] www.legislation.gov.uk/uksi/2017/267/pdfs/uksi_20170267_en.pdf Part 1 of the Schedule specifies regulatory functions exercisable by specified named regulators. Part 2 of the Schedule specifies regulatory functions exercisable by regulators who are not named but are included by virtue of legislation under which they exercise regulatory functions. Part 3 specifies regulatory functions exercisable by a Minister of the Crown.

[26] www.nao.org.uk/report/principles-of-effective-regulation/

[27] www.gov.uk/government/publications/the-benefits-of-brexit

Source	Principles
	where it can. When strong rules are required to achieve the best outcomes, the UK will act decisively to put them in place and enforce them vigorously. **Recognising what works:** The UK will thoroughly analyse our interventions based on the outcomes they produce in the real world and where regulation does not achieve its objectives or does so at unacceptable cost, the UK will ensure it is revised or removed. **Setting high standards at home and globally:** The UK will set high standards at home and engage in robust regulatory diplomacy across the world, leading in multilateral settings, influencing the decisions of others and helping to solve problems that require a global approach.
Taskforce on Innovation, Growth and Regulatory Reform (2021)[28]	**Proportionate:** Regulators should scale their support and requirements appropriately to risk and the size of firms **Forward-looking:** Regulators should focus on future growth and risk, actively shaping technological and market developments **Outcome-focussed:** The UK should focus on building technology-neutral regulatory regimes that focus on goals and outcomes rather than inputs. **Collaborative:** Regulators must engage with businesses, including SMEs and start-ups, empower innovators and connect with their peers and the public. **Experimental:** Regulators should make space for businesses to test and trial new business models, products and approaches**.** **Responsive:** Regulators should take an iterative-learning approach to new and uncertain market developments.

Principles for Regulation and Innovation

Source	Principles
2018 - Principles for regulating emerging technologies Deloitte[29]	**Adaptive regulation:** Shift from "regulate and forget" to a responsive, iterative approach.

[28] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/994125/FINAL_TIGRR_REPORT__1_.pdf

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

	Regulatory sandboxes: Prototype and test new approaches by creating sandboxes and accelerators. **Outcome-based regulation:** Focus on results and performance rather than form. **Risk-weighted regulation:** Move from one-size-fits-all regulation to a data-driven, segmented approach. **Collaborative regulation:** Align regulation nationally and internationally by engaging a broader set of players across the ecosystem.
2019 - Regulation for the Fourth Industrial Revolution[30] - Government White Paper	The White Paper identified several themes in reforming regulation in response to technological innovation: The UK needs to be on the **front foot** in reforming regulation in response to technological innovation. The regulatory system is **sufficiently flexible and outcomes-focused** to enable innovation to thrive. Enable **greater experimentation**, testing and trialling of innovations under regulatory supervision. Support innovators to **navigate the regulatory landscape** and comply with regulation. Build **dialogue with society and industry** on how technological innovation should be regulated. **Work with partners across the globe to reduce regulatory barriers** to trade in innovative products and services.
2019 – NESTA Report on Anticipatory Regulation[31]	**Inclusive and collaborative:** Engage the public and diverse stakeholders where new technologies raise ethical issues with sensitive political implications, and leverage the capabilities of businesses, cities, and civil society to secure policy goals. **Future-facing:** Develop resilient, adaptive strategies that can cope with the inherent uncertainty of fast-changing markets. **Proactive:** Engage with innovators and innovation early to enable timely, proportionate responses to issues that may scale rapidly. **Iterative mindset:** Take a test-and-evolve rather than solve-and-leave approach to novel problems.

[30] www.gov.uk/government/publications/regulation-for-the-fourth-industrial-revolution/regulation-for-the-fourth-industrial-revolution

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

	Outcomes-based: Focusing on validating companies' efforts to achieve well-defined goals, rather than setting rules, and incentivising platforms to support regulatory objectives. **Experimental:** In facilitating diverse responses to the regulation of early-stage opportunities and risks, and where national or global policies and standards are still to be established.
2021 - Digital Regulation Principles for regulating digital technologies[32]	**Actively promote innovation:** Consider non-regulatory measures like technical standards to reduce burdens. Where regulation is needed, should be designed to minimise unnecessary burdens on businesses. To do this, it should be outcomes-focused, backed by robust evidence, and consider the effects of proposed policies on innovation. **Achieve forward-looking and coherent outcomes:** The fast-moving, cross-cutting nature of digital technologies means that previously distinct regulatory regimes may become increasingly interconnected - for example in content, competition, and data protection. **Exploit opportunities and address challenges in the international arena:** Digital technologies present global solutions and global problems in a way rarely seen in other sectors. Policymakers will therefore build in international considerations from the start, taking account of our existing international obligations, likely future agreements, and the impact of regulations and standards developed by other nations.
2021 – OECD; Recommendation for Agile Regulatory Governance to Harness Innovation[33]	Developing or adapting governance frameworks and regulatory approaches so that they are forward-looking by developing institutional capacity and assigning clear mandates, accordingly, conducting **systematic and co-ordinated horizon scanning and scenario analysis**, anticipating and monitoring the regulatory implications of high-impact innovations, and fostering continuous learning and adaptation. Developing more **outcome-focused regulatory approaches** to enable innovation to thrive by harnessing the opportunities offered by digital technologies and big data. Harnessing, under the condition that corresponding outcomes can be appropriately monitored, the opportunities provided by **non-legally binding approaches** either as an alternative or as a complement to other regulatory instruments. Enabling **greater experimentation, testing, and trialling** to stimulate innovation under regulatory supervision.

[32] www.gov.uk/government/publications/digital-regulation-driving-growth-and-unlocking-innovation/digital-regulation-driving-growth-and-unlocking-innovation#ministerial-foreword

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

Conclusions

Regulators carry out a range of functions including making sure individuals have the necessary qualifications and/or experience to practise the profession and taking any necessary enforcement action[34]. The Regulators' Code[35], under the Legislative and Regulatory Reform Act 2006 aims to provide a clear, flexible and principles-based framework for how regulators should engage with those they regulate. Regulators within scope of the Regulators' Code are diverse but they share a common primary purpose – to regulate for the protection of the vulnerable, the environment, social or other objective.

There are several general principles identified for better regulatory practice, however, it is unclear whether there is a hierarchy or if they should complement each other. Furthermore, some of the principles are enshrined in legislation and some are not, but that is not necessarily an indicator of importance. For example, the five principles of Good Regulation developed in 1998 is well established and impactful despite not being underpinned by legislation.

Overall, principles such as *proportionality*, being alive to *risk* and regulators being transparent or accountable are perfectly compatible with the broader goal of enabling innovation, even though they have not been developed specifically with innovation in mind. Reflecting on the body of regulatory principles does, however, suggest that the impact of regulation on innovation may not have been considered. For example, the 2014 Regulators' Code cites 'risk' eleven times but does not mention innovation once. There is some evidence, however, that the link is being increasingly recognised. The Principles of Regulation published in 2022, for example, explicitly references the role that regulation can play in cultivating innovation.

In assessing the existing principles for regulation and innovation published by numerous bodies above, we noted several strong overarching themes including:

- **Collaboration:** The uncertainty associated with how innovations are adopted heightens the importance of engaging with other regulators, the public, academia, businesses (incumbents and new entrants), innovators, and international bodies in the design and implementation of regulation.
- **Retaining a degree of proportionality, and adaptability:** Regulation that is proportionate by taking account of both risks and benefits is often cited as important. The fast-moving nature of technological innovation necessitates a need for continuous regulatory experimentation, learning and adapting.

[34] www.gov.uk/government/publications/professions-regulated-by-law-in-the-uk-and-their-regulators/uk-regulated-professions-and-their-regulators

[35] www.gov.uk/government/publications/regulators-code

- **Outcomes focused:** Several publications highlight the importance of taking an outcome focused approach with an emphasis on avoiding prescriptive regulation, where appropriate and the usefulness of non-legislative measures such as standards.
- **Future facing:** A final key theme revolves around being proactive in anticipating and monitoring future technological innovations and considering early on possible regulatory implications if any.

Recommendation 1

The Government committed to delivering a 'renewed regulatory framework nested under its five principles' in the 'Benefits of Brexit' publication. The Council recommends that the Government (Better Regulation Executive[36]/ Brexit Opportunities Unit[37]) ensures that the four overarching themes of regulation and innovation, as highlighted in this report, permeate through in the renewal of this framework.

Recommendation 2

The Council welcomes the recent launch of the Institute of Regulation[38], and recommends the Institute and the UK Regulators Network[39] work with regulators, academics, and innovators, where appropriate, to design and provide training resources/courses for regulatory professionals on best practice on regulation and innovation. This should include theoretical and practical elements.

[36]The Better Regulation Executive (BRE) leads the regulatory reform agenda across government. www.gov.uk/government/groups/better-regulation-executive

[37] The Brexit Opportunities Unit exists to make the most of the economic and political opportunities of Brexit – making sure policy, laws and regulations are helping to boost growth, drive forward innovation and increase competition in the UK: www.gov.uk/government/news/search-for-head-of-the-new-brexit-opportunities-unit-begins

[38] https://ioregulation.org/about-us/

[39] www.ukrn.org.uk/about/

4. Closing the Gaps

In this section, we set out areas of regulatory design and implementation where we see the most significant gaps between the four key overarching themes underpinning regulation and innovation, and what is happening today. In highlighting these points for particular focus, we are not implying that there is no good regulatory practice here – indeed, our case studies show the inverse.

We have observed that these are areas where regulators and policymakers find it hard to act in line with what the principles imply or where innovators feel frustrated. We believe that focusing on these areas for improvement would act as an enabler for innovation across the regulatory landscape.

Specifically, we believe those points of focus relate to the need for regulation and regulators to:

- Be proportionate and balance potential benefits and risks;
- Integrate ethical considerations and outputs from public and relevant stakeholder dialogue;
- Take account of commercial considerations and the need to attract investment;
- Include alternatives forms of regulation;
- Get the timing right;
- Cultivate a culture of openness and a growth mindset.

In the following section we discuss each in turn. We unpack each point in ways we hope will help regulators and policymakers – but also innovators and others – to understand why it matters and how improvements in regulatory design and practice might be achieved. We provide links to case studies that are relevant to each area of focus, which should bring to life some aspects of good practice, and in doing so we hope to provide practical help and guidance for regulators and policymakers.

Focal point 1: Regulation should adopt a proportionate approach to risks and benefits

Why does this matter for regulation and innovation?

The principle of **proportionality** has a long legal and ethical history of application in the context of regulatory decision making generally. Proportionality is one of the principles that is explicitly named in both the longstanding principles for good regulation published in 1998[40] and the principles for regulation published by the Government in 2022[41]. It is an important legal principle and closely related to the need for a balancing process to take account of the relative interests and norms of affected parties[42].

Proportionality has also been described as "an ethical approach to resource allocation during the Covid-19 pandemic", requiring that responses should be proportional to the good that can be achieved and the harm that may be caused and emphasising its relationship to a wide range of related ethical principles[43]. The above examples demonstrate that the principle of proportionality is used in different ways depending on **what** is the context of the decision being taken; **who** is taking the decision and who will be affected by it; and **how** it is expected to be implemented.

What are the biggest gaps and how can they be addressed?

There is a challenge in taking a 'proportionate' approach to new technological innovation when the nature and extent of the potential risks/benefits may not be clear, for example with more disruptive innovations. This uncertainty can lead to regulatory systems becoming unnecessarily precautionary[44] and attending disproportionately to the risks of using new technologies, and thereby impeding innovations that could benefit the UK. Here, we focus on three issues: the assessment of risk and benefit, choosing the right tool for the job and doing nothing.

It is important to note that there is a distinction between a new technology, and the applied use of that technology. In a report the Government Office for Science[45] outlines that

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[40] https://webarchive.nationalarchives.gov.uk/ukgwa/20100407173247/http:/archive.cabinetoffice.gov.uk/brc/upload/assets/www.brc.gov.uk/principlesleaflet.pdf

[41] www.gov.uk/government/publications/the-benefits-of-brexit

[42] Duarte, D. and Sampaio, J.S. (eds) (2018) *Proportionality in Law: analytical perspective*. Springer https://link.springer.com/book/10.1007%2F978-3-319-89647-2

[43] Article by Kate Jackson-Meyer, Ph.D. on 'bio ethics today' regarding the Ethical Approach to Resource Allocation During the COVID-19 Pandemic: https://www.bioethics.net/2020/04/the-principle-of-proportionality-an-ethical-approach-to-resource-allocation-during-the-covid-19-pandemic/

[44] https://ec.europa.eu/environment/integration/research/newsalert/pdf/precautionary_principle_decision_making_under_uncertainty_FB18_en.pdf

[45] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/381905/14-1190a-innovation-managing-risk-report.pdf

discussions around new technology should be founded around specific possible uses of the technology, their respective alternatives, and the costs of inaction as well as action. This is an important concept when considering the principle of proportionate regulation.

The assessment of risk

When considering introducing or changing regulation or making an intervention (such as an enforcement decision) based on existing regulatory frameworks, regulators or policymakers must seek to develop a nuanced understanding of the problem they are trying to solve, which would cover several key dimensions.

The first concerns **what harm would occur** if the risk under examination crystalised.

This would include **an assessment of whether the harm would be large or small**. Assuming other metrics remain equal, a greater harm could justify more costly interventions to prevent it. When we talk here about 'costly' interventions, we include all forms of 'cost', financial and non-financial, direct and indirect, and including opportunity costs.

Assessing the potential scale of harm would include an assessment of different types of detriments, including financial but also to health or to the environment. Looking beyond financial detriments clearly presents a challenge in terms of quantifying potential harm, but even where quantification is difficult, it is important for regulators and policymakers to undertake some assessment of scale.

Identifying a large potential harm is not sufficient to justify costly regulatory intervention – **it is also important to understand the nature of the potential harm**. This will include whether the harm is temporary or permanent, reversible or irreversible, and whether it is something that lends itself to compensation. Other things being equal, substantial harm that is permanent, irreversible, and not susceptible to other forms of compensation will more likely justify greater costly regulatory intervention than transient, reversible harm, which may be compensated.

Further, it is important to identify **who would suffer the harm in question**. Intervention may be more justified where the harm is experienced by groups in society who are less able to take steps to protect themselves against such harm, or to recover from it. Such groups could include those in circumstances that create some vulnerability[46]; they may also include future generations[47]. The groups that are at risk of harm, may not be those who would benefit from the activity in question.

[46] See for example the FCA's Occasional Paper No 8 on 'Consumer Vulnerability' from February 2016, available at: www.fca.org.uk/publication/occasional-papers/occasional-paper-8.pdf

[47] As encapsulated in the Welsh Government's 2015 Wellbeing of Future Generations Act, see: www.futuregenerations.wales/about-us/future-generations-act/

It is also important to understand the **proximity and pace of the risk** in question. We discuss below the importance of deciding to 'do nothing' as a valid regulatory choice. Whether regulators should do nothing, or perhaps more accurately maintain a watching brief, rests on understanding whether potential harm, of a scale and nature that would justify regulatory action, is imminent or far away. If it is far away, the pace at which it is moving should be taken into consideration. A judgement on the proximity and velocity of a risk could reflect, for example, the pace of acceptance of uses for a new technology.

Finally, regulators should understand the **transmission mechanism,** i.e., the chain of events and interactions, that would ultimately result in harm arising. Without understanding this, regulators and policymakers will simply not have visibility of the full set of options available to them to address the harm, which creates a risk that they will not choose the least costly and burdensome intervention that will address it. For example, if misuse of a new technology could result in harm, a regulator could seek to prevent the new technology from coming to market or instead take steps to prevent or reduce the likelihood of misuse.

Choosing the right tool for the job and having regard to any risk to innovation

Once a regulator or policymaker has understood the nature of the risk that they are considering addressing through regulation, they must consider what form of intervention is appropriate. The principle of proportionality requires that they should choose the tool that will do the job with the lowest overall cost. This is not as simple as it sounds – it may be that they are faced with a choice between a costly intervention with a high probability of addressing the risk and a less costly intervention with a lower probability of addressing the risk.

Given that our aim is to better enable and encourage regulation that is supportive of innovation, it is our strong view that **regulators and policymakers should explicitly consider the impact that different regulatory interventions could have on innovation**. In our view, this is a necessary element in the successful application of the principle of proportionality. For an intervention to be proportionate, it is not sufficient that the cost of the intervention is proportionate to the reduction in the risk of harm it would achieve; **it is also necessary to consider the *risk* that the intervention itself poses**. This would include the potential impact on benefits from a particular innovation that might be foregone; it would also include the potential creation of a 'chilling effect'[48] on innovation more generally.

There is scope for such consideration within existing guidance on regulatory cost-benefit

[48] In a legal context, a chilling effect is the inhibition or discouragement of the legitimate exercise of natural and legal rights by the threat of legal sanction: www.opensocietyfoundations.org/uploads/c8c58ad3-fd6e-4b2d-99fa-d8864355b638/the-concept-of-chilling-effect-20210322.pdf

analysis[49]. We note that while the 'full route impact assessment' set out includes quantified assessment of the costs to business and societal value, and list of other factors to be considered, the *impact on innovation* is not explicitly referenced or clearly covered in any wider factor. The Government proposed in its recent consultation[50] streamlining Impact Assessments (IAs) to focus on the cost-benefit analysis while the discursive elements of IAs could be replaced by 'success criteria'[51] and we note in the consultation response that 63% of those who responded felt this approach would not capture enough information on impacts. In the Benefits of Brexit paper[52], the government has also outlined intentions to take a holistic and efficient approach to scrutinise the impacts of regulation on consumers, businesses, barriers to entry and international trade, innovation and delivering on our net zero ambitions.

In many circumstances, there will be uncertainty about the future benefits and harms, and the unacceptable nature of an anticipated harm may be driving the consideration of regulation. The benefits, including from innovation, may be foregone because of the regulatory intervention. Regulators and policymakers should therefore incorporate a step in their assessment of potential regulatory interventions that explicitly considers its impact on innovation, in addition to the expected focus on risk.

Regulatory interventions could enable or hinder innovation in the following ways:

- restricting choice of technology (either proscribing some or specifying others);
- Creating a default position whereby a new technology would not be able to enter the market (e.g. because prior approval is required);
- Creating an approvals regime that looks beyond a track record of historical performance data, which otherwise would make it difficult or impossible for a new or disruptive technology to amass;
- Otherwise resulting in long delays and/or very high costs to the company before a new technology could access the market;
- Unnecessarily bringing a new technology under the scope of the regulatory regime that applies to companies whose business model would be threatened by the new technology (and which may be able to use their existing expertise and relationships in respect of that regime to their competitive advantage);

[49] See for example the Regulatory Policy Committee's Proportionality guidance for departments and regulators, available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/800603/Final_proportionality_.pdf

[50] www.gov.uk/government/consultations/reforming-the-framework-for-better-regulation

[51] A short statement of expected outcomes from the regulation for it to be deemed successful at achieving its stated purpose, and a concrete evaluation plan setting out how these outcomes will be measured over time

[52] The Benefits of Brexit policy paper: www.gov.uk/government/publications/the-benefits-of-brexit

- Subjecting firms developing new technology to significant regulatory risk (which could jeopardise investment in that new technology) either by not being clear about how regulation applies to it or by including new technology within a regulatory regime that is not suitable for it (and which is therefore unsustainable and/or creates unintended consequences).
- Creating clarity and as much regulatory certainty as possible for innovators that could facilitate investment.

Our proposal to account for innovation within regulatory impact assessments is not new. We noted the Government in the White Paper for the Fourth Industrial Revolution committed to piloting an innovation test so that the impact of legislation on innovation could be captured when developing and accessing policy options. Furthermore, Google UK, in an economic impact report on making the UK the best place in the world to run digital businesses, recommended 'introducing Innovation Impact Assessments to better measure the full impact of new and existing regulation'[53].

It is clear too, if regulators and policymakers are to choose the most proportionate tool for the job, they must look broadly across **the full range of the regulatory and policy tool kit**. Some tools will be more familiar to regulators and policymakers than others, and it is easy for the familiar to become the default. Government departments might most easily consider the preparation of legislation. Enforcement authorities might most easily consider investigations and enforcement action. Economic regulators might prefer price controls and economic incentives.

In general, flexibility is more likely to support innovation than rigidity, and flexibility is often found at the softer end of the regulatory tool kit. Legislation can take many years to draft and is hard to change once in place. Rules and standards will be easier to adapt than legally based regulations and are less flexible than 'best practice' guides, which can be helpful in providing clarity but is easy to adapt in the face of change. Regulators are also aware of the power of speeches and blogs in raising issues and setting expectations. We discuss the merits of alternatives forms of regulations below in a section dedicated to this question.

We note that in the consultation on reforming the better regulation framework[54] the UK government states that: "Where markets achieve the best outcomes, we will let them move freely and dynamically. We will pursue non-regulatory options where we can. When strong rules are required to achieve the best outcomes, we will act decisively to put them in place

[53] https://googleimpactreport.publicfirst.co.uk/uk/

[54] Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1005119/reforming-the-framework-for-better-regulation.pdf

and enforce them vigorously." This seems to us to be precisely encouraging regulators to look across a full and broad range of tools, which we support.

It is common for some form of consultation to be undertaken by a regulator or policymaker to inform a regulatory intervention, concerning matters such as the nature of the risk to be addressed and the regulatory tools to address it. It is critically important they **seek out views beyond the existing players**. This will help regulators and policymakers to consider the impact of the interventions they are considering in different ways of doing things. This is particularly important because existing players may have a strong interest in creating barriers to technology innovation, where this would create new sources of competition. It is precisely these existing players that are likely to be more expert in the regulatory regime and familiar with existing relationships that may enable them to make powerful arguments that entrench existing regulations.

In some circumstances, regulators and policymakers may look to industry to devise the approach to regulation, as happens for example with standards. These approaches can be useful in helping to ensure that the impact on business is factored into regulatory design. Again, it is important to ensure that undue advantage to existing technologies is not given by virtue of the existing regime having been developed with them in mind. Where such approaches are adopted, those setting the rules or standards must be appropriately representative not only of existing technologies and business models, and the interests of the firms that use them, but also of innovators. If these groups cannot be adequately represented in the engagement process, it is incumbent on the decision maker to recognise this and factor into their decision the potential for bias this introduces.

'Do nothing' is an option

The final observation we make on the application of the proportionality principle is that 'do nothing' is an option that should be taken seriously. Just because a risk has been identified, it does not automatically follow that regulation will make it better. We note that consideration of the 'do nothing' option is an explicit requirement for regulatory cost benefit analysis, as set out in guidance from the Regulatory Policy Committee[55]. We can see that it is a difficult option for any regulator or policymaker, especially when faced with apparent and immediate harm. Regulators regulate; governments make policy and seek to enshrine it in legislation. To forbear in the face of harm is not just a politically difficult choice to make, but one that appears to go against the core objectives of an institution, for example, to reduce the risk of harm.

The key to a proper assessment of the 'do nothing' option is to recognise that, in reality, it is not about doing nothing. First, it represents a conscious choice based on the evidence

[55] www.gov.uk/government/publications/proportionality-in-regulatory-submissions-guidance

and analytical processes we have discussed above. This option should be chosen when other options would entail significant risk of doing more harm than good.

Second, where a decision is made to refrain from regulatory intervention when there is a risk of harm, the regulator or policymaker is highly unlikely to abandon the issue altogether. Especially when the decision is made to hold back from regulating in the face of technological change, regulators and policymakers are likely to – and should – maintain an active 'watching brief'. This will enable an alternative course of action to be taken should the harm-benefit balance change. This enables regulators and policymakers to learn how new technology is used and developing, what enables it and how it affects existing technologies and business models.

It is worth highlighting that both regulators and policymakers can assess and do conclude that 'do nothing' is the right option. This can, however, go un-noticed as the system does not require them to submit an Impact Assessment when there are no changes proposed.

Recommendation 3

Cost-benefit analysis and regulatory impact assessments should always include an assessment of the impact of the relevant regulatory intervention on innovation and this should be taken into account in deciding if and/or when an intervention should go ahead. The Better Regulation Executive, working with HM Treasury, Cabinet Office, and the Regulatory Policy Committee should develop and implement guidance for regulators and policymakers on how this should be done. The Council is willing to help in the design and implementation of this.

Case studies for 'Regulation should adopt a proportionate approach to risks and benefits'

In this segment we have included some case studies that demonstrate positive, negative, or unintended consequences of actions when trying to comply with this focal point.

- Agile governance of self-driving cars in Japan
- EU End-of-Life vehicles directive
- EU REACH Regulation
- Forbearance: Ofcom and access prices for final mile fibre

Focal point 2: Regulation and innovation should embrace ethics and public engagement

Why does this matter for regulation and innovation?

Effective, proportionate regulation, which helps to build trust, is an important element in creating an environment that fosters innovation. Without regulation, innovators could struggle to get fair access to markets or financial investment to support product development. Additionally, society might also distrust new ways of doing things and might be reluctant to adopt them, and if adverse consequences from new technology should emerge in future, regulatory over-reaction might lead to unnecessary, more draconian regulatory interventions.

There is a great deal of science around regulation. Metrics are established, measurements are taken, data are collected, models are built, theories are used to analyse the past and predict the future. All regulation, however, involves judgements made by human beings.

Most regulatory regimes reflect the accumulation of a huge number of judgements over time. These regimes have their basis in statute, conferring a set of aims and objectives on a regulatory body that must pursue them using its given powers. These duties and powers bound and shape the regulators' freedom to act. Even acting within a statutory framework, regulators have significant discretion[56] in respect of what they focus on, which tools they prefer, how specific decisions are made and enacted, and how and on which topics they communicate. Similarly, innovators have choices about the ideas they pursue through start up and into scale. They have choices about the business models they adopt. The objectives and tolerances they design to and the metrics they use to judge success reflect value judgements. Similarly, like regulators, innovators also have choices about how they come to those judgements. This section focuses on three issues: the value of an explicit ethical framework for regulation, public engagement as a critical enabler of trust and ethics and public engagement for innovators.

What are the biggest gaps and how can they be addressed?

The value of an explicit ethical framework for regulation

Given the importance of judgement in regulation – in determining what the rules say, their significance and how they are interpreted and translated into action - public bodies,

[56] It is important to note, given the breadth of their discretion, that regulators are held to account for what they do and how they do it. Their decisions are subject to judicial review, and in some cases, special appeal regimes. Where regulators are independent of government, they are accountable to parliament, in particular via the relevant select committees of MPs and members of the House of Lords. They are held to account for making good use of public money by the National Audit Office and the Public Accounts Committee. They are also, more broadly, held to account by their stakeholders and the wider public, including via the media.

including regulators, do and should make ethical considerations. These considerations include questions around 'fairness' as well as about how safe is 'safe enough', and wherever a value is placed on life for the purpose of a cost benefit analysis[57]. They arise whenever regulators or policymakers balance the interests of different groups in society.

It is necessary for regulators to be aware that they are making judgement calls and to be thoughtful about how they are making them. Clear statements about the principles being adopted as the basis for decision-making are very useful[58]. Where regulation is conducted with an emphasis on pragmatism – which we believe is helpful in enabling innovation – it is likely to involve greater exercise of judgement, which makes it even more important to be clear about how this is being done.

We would therefore encourage regulators to be as explicit as possible about the frameworks they use to make judgements, what they believe they are trying to achieve, what they think of as desirable and undesirable, and the assumptions they are making. In short, to be as explicit as they can about their ethical approach. For example, we note there is existing guidance to help public bodies including regulators use data ethically and how to use automated or algorithmic decision-making systems in a safe, sustainable and ethical way[59]. Understanding the ethical framework used by regulators, will allow regulated bodies to align their decision-making processes. This will reduce uncertainty and simultaneously allow regulators to make clearer distinctions between 'allowable' or 'enforceable' actions.

Public engagement as a critical enabler of trust

In 2021, BEIS published a research paper on the use of public engagement for technological innovation[60]. The paper outlined that public engagement is a broad term that is used in a variety of sectors (e.g. in research, healthcare and policymaking). It includes different mechanisms which allow members of the general public to engage on issues that are of public importance. In the context of technological innovation, public engagement is used to describe the involvement of a diverse group of people (the general public, but also other key groups such as lobbyists, civil society organisations and social influencers) in discussions and debates about potential applications of new and emerging technologies,

[57] www.gov.uk/government/publications/valuation-of-risks-to-life-and-health-monetary-value-of-a-life-year-voly/annexe-5

[58] This is set out in: *Annual Report of the Government Chief Scientific Adviser, 2014. Innovation: Managing Risk not Avoiding It. Evidence and Case Studies*, pp 129-136. London: Government Office for Science, available at: www.gov.uk/government/publications/innovation-managing-risk-not-avoiding-it

www.gov.uk/government/publications/data-ethics-framework - Guidance for public sector organisations on how to use data appropriately and responsibly when planning, implementing, and evaluating a new policy or service.

[60] https://www.gov.uk/government/publications/the-use-of-public-engagement-for-technological-innovation-literature-review-and-case-studies

their governance, regulation and the wider issues that could arise from the way that they are developed and adopted.

In considering how regulation can best enable and support getting the best value from technological innovation, we have identified stakeholder and wider public engagement as an area that would benefit from further focus. Broadly, there are three elements to this.

The first element of this concerns ***who* regulators engage with**.

Unsurprisingly, regulators spend most of their time engaging with those who are currently most affected by their regulation. Regulators need to engage with firms they currently regulate in order to understand whether, how, and to what extent, their regulation will translate into behaviour change on the part of those firms, ultimately achieving their public interest goals. These firms are generally well incentivised, well-informed and well-resourced to engage with regulators. Those, however, who are currently subject to regulation may not be best placed to help the regulator to understand and adapt to innovative approaches. Whilst it is true that large, incumbent firms do innovate, they also have business models and incentives that are quite different from smaller firms. They will inevitably see the world more through their own eyes than through the eyes of a smaller disrupter. Those with new products or new ways of doing things or new business models may not even be aware of regulation, let alone know how to engage in a dialogue with a regulator or policymaker. So, unless the regulator or policymaker seeks them out, their voice will always be less heard than that of the larger incumbents.

Similarly, regulators' and policymakers' engagement with the public is often through civil society groups. These groups can play an important role in synthesising views and coming up with practical proposals, however, they are institutions in their own right, with their own interests, which affect their advocacy. It is important for regulators and policymakers to keep this in mind. It can be easy for regulators and policymakers to become used to engaging with certain groups and to view engaging with them as a shortcut to public engagement. Especially in the context of engagement on disruptive, transformational technological, perhaps different groups in society might be uniquely affected – positively and negatively – and engagement requires a much wider lens.

Linked to this, we observe a second element of this gap in ***how* regulators and policymakers engage**. The traditional modes of regulatory engagement require a great deal from the interlocutor, specifically:

- To know that they are interested in regulation;
- To know where to find information about the regulation they are interested in;
- To be able to understand the information available;
- To understand the regulatory process, so as to know when and how to engage effectively.

This is symptomatic of a general approach in which regulators and policymakers create their own conversation and then invite others to participate on the terms that the regulator or policymaker has set out. This approach can often fail at the first hurdle where engagement activity is not represented in earlier stages.

We would encourage regulators and policymakers to adjust the balance of their effort from 'talking to, explaining, and getting support' more towards 'dialogue, listening to, understanding, and seeking challenge'. This would improve the effectiveness of any regulatory system, in line with anticipatory regulatory principles, making it better at horizon scanning, improving understanding of risks and benefits, and improving the robustness of decision-making in different scenarios. It could also help to improve trust in regulatory decision-making.

There is a wealth of thinking on public engagement that regulators and policymakers can harness. A non-exhaustive list, but good starting points, include:

- Nesta, e.g. their Seven Principles for Public Engagement in Science and Innovation Policymaking[61];
- National Coordinating Centre for Public Engagement, which is focused on helping universities engage with the public, but has many tools that are relevant more broadly[62];
- The use of public engagement for technological innovation[63];
- Involve, a charity whose purpose is to put public engagement at the heart of decision-making[64];
- TIGTech, a research organisation focused on ensuring that governance of technology embraces considerations of benefits, risks and public trust[65];
- The British Standards Institute, in their Responsible Innovation Standard[66].

We have heard from different regulators about how they are seeking to widen engagement beyond the 'usual suspects'. Most regulators in our survey sample indicated that, beyond typical engagement with other regulators, the general public and academics, they are also

[61] Available at: https://media.nesta.org.uk/documents/Seven_principles_HlLwdow.pdf

[62] See: https://publicengagement.ac.uk

[63] www.gov.uk/government/publications/the-use-of-public-engagement-for-technological-innovation-literature-review-and-case-studies

[64] See: www.involve.org.uk/about Their nine principles of public engagement from 2011, still have much to recommend, and are available at: https://www.involve.org.uk/resources/publications/practical-guidance/deliberative-public-engagement-nine-principles

[65] See: www.tigtech.org/ Their thinking on a more engaged, collaborative and communicative approach to tech governments has wide relevance, and is available at: https://static1.squarespace.com/static/5fc12cea2cf09257bd6dcc01/t/5fca5150ac031d3c8e89ff06/1607094623935/Trust_and_tech_governance.pdf

[66] See: https://pages.bsigroup.com/l/35972/2020-03-17/2cgcnc1?utm_source=pardot&utm_medium=email&utm_campaign=SM-STAN-LAU-PAS-PAS440-2003

engaging with start-ups and innovators[67]. We have, however, heard from many innovators that they consider the extent, nature and depth of their dialogue with regulators currently to be inadequate. This leaves them concerned that regulators may not understand their innovation or the implications it could have, and therefore may not be well placed to regulate in a way that will reflect an appropriate balance of interests.

Our focus on technological innovation has meant that we are attracted to the idea of a 'deliberative space' as a mode of public engagement. This involves the creation of an inclusive, easily accessible space that enables wide participation in an ongoing conversation about people's hopes, fears, aspirations and concerns, and indeed their questions about new technology. This would enable regulators to both listen to an unmediated conversation and also to use the space to prompt conversations on particular topics where they would be interested to learn more. We have seen this concept specifically referred to in respect of the need for societal deliberation in respect of neurotechnologies[68]. We can, however, see a wider relevance where regulation meets technological innovation and where choices must be made about how to respond.

The third, and final element of the public engagement gap relates to ***when*** **regulators and policymakers engage**.

Although regulators do typically consult on their annual work programmes, most substantive consultation is on proposals that have already been developed by regulators and policymakers. It is true that some consultations are more open-ended and are more at the 'problem definition' or 'optioneering' stage of the process. In many cases, however, regulators and policymakers engage widely (e.g. by publication of a consultation document) on proposals in which they have already invested a great deal of time and effort, and which have been formed by means of engagement with a smaller group of stakeholders. This means that options have already been whittled down, such that it is harder to influence from beyond the 'choice set' and increasing the risk of path dependency in decision-making (and a desire to avoid writing off intellectual 'sunk costs').

We would therefore encourage regulators and policymakers, perhaps using some of the techniques referred to above, to engage more broadly earlier on in the design of regulation. This is something that the Medicines and Healthcare Products Regulatory Agency (MHRA) does, using among other techniques, patient consultative groups in its decision making[69]. Regulators and policymakers could use earlier broad engagement to improve their understanding of risks and benefits, perhaps as they relate to a new technology, as well as to test their proposals on how a problem already defined should be

[67] 10 of 18 regulators within the sample.

[68] See for example: www.oecd-forum.org/posts/57641-new-frontiers-of-the-mind-enabling-responsible-innovation-in-neurotechnology

[69] See for example: www.gov.uk/guidance/opportunities-for-patients-and-the-public-to-be-involved-in-the-work-of-the-mhra

solved. They could also test out at early stages the potential for co-creation of regulatory approaches.

Ethics and public engagement for innovators

Our focus is on regulatory reform that will enable the UK to get best value from technological innovation. This means we are predisposed to make recommendations to regulators and policymakers about regulation. We are, however, also conscious that regulation does not achieve outcomes alone, but rather, by means of continuous interaction between regulators, innovators, and wider society. It feels important to us to be clear that those involved in innovation have a key role to play in supporting the kind of regulation that will enable their innovations to be successful and deliver value across society.

The best way for those involved in innovation to do this is to take ownership *themselves* of ethical considerations. The more innovators building ethical considerations into the process by which their idea moves into concept, start up, and scale, the more able regulators and policymakers will be to step back and maintain a watching brief rather than intervene. This requires innovators not only to be explicit about their values and how they are applying these in what they do, but also to be able to demonstrate that the governance of their innovation supports this.

In a nutshell, innovators can play their part in creating an environment of trust, which will help support their innovation, by being trustworthy. This relates to the nature of their products and services, but also to the process by which those products and services are created. Transparency is also an important element of trustworthiness. In the textbox below, we further discuss trust, trustworthiness and regulation.

There are frameworks that can help innovators to do this. The UKRI's framework for responsible innovation[70] seeks to promote creativity and opportunity for science and innovation that are socially desirable and undertaken in the public interest. This includes the 'AREA' principles of anticipate, reflect, engage and act, and links to resources to support researchers in applying these. The Nuffield Council on Bioethics[71] is helpful in exposing the ethical issues associated with a wide variety of topics connected to the life sciences and public policy. There is also a Responsible Research and Innovation (RRI) community of practice that has developed useful tools in this area[72]. The RRI's work has primarily focused on responsible research in universities and research institutes. The BSI's

[70] Available at: https://epsrc.ukri.org/index.cfm/research/framework/

[71] See: www.nuffieldbioethics.org/

[72] Available at: https://rri-tools.eu/

Responsible Innovation Standard (PAS 440) focuses more on innovation and provides a useful tool kit in this context[73].

For their part, regulators and policymakers could do more to reflect how an innovation is being developed, implemented, and promoted in their regulatory design and decision-making. If a regulatory regime were able to give some credit or take some assurance from the ethical approaches, governance models and public engagement conducted by those driving the innovation, this could encourage more ownership of such issues by innovators themselves, as well as enabling regulation to be more flexible and therefore supportive of innovation[74]. This could lead to more of a virtuous circle.

Trust, trustworthiness and regulation

Trust is a critical enabler of successful business. If an innovation is to move successfully from concept to start up to scale, it must on some level be trusted. We believe regulation can be an important enabler of trust in innovative technologies. It is also important to unpack the different elements of trust and the role regulation can play:

Substance: This relates to the nature of the product or service being provided. To trust the product or service, those who use it or interact with it should feel confident that they will not be unduly harmed (i.e., if there is a risk then this should be clear, and the user should be able to respond to that information). The user should feel confident that the product or service will do what the provider has said it will do.

Process: The process by which a new technology is developed, used, sold, or regulated can help to build or undermine trust. If, for example, it is understood that a new medicine has been appropriately tested before being marketed, this will help to build trust in its use. If people, for example, are aware that there is a regulatory regime in place that ensures products are safe or regulates the prices of monopoly services, they feel reassured that their interests are being safeguarded. If people know that there are processes in place to provide redress if something goes wrong, they may be more prepared to make a purchase.

Transparency: It is easy to understand the importance of transparency in building trust when we acknowledge how much secrecy and covertness undermines it. If transparency is

[73] See: https://pages.bsigroup.com/l/35972/2020-03-17/2cgcnc1?utm_source=pardot&utm_medium=email&utm_campaign=SM-STAN-LAU-PAS-PAS440-2003

[74] This would be line with the 'ethical business regulation' approach as set out in C. Hodges and R Steinholz (2017) *Ethical Business Practice and Regulation: a behavioural and values-led approach to compliance and enforcement*, Bloomsbury. This approach is being taken up more generally by some regulators, such as Ofwat, see: www.ofwat.gov.uk/vision-waterstories/news/7-things-you-need-to-know-about-ethical-business/

really to build trust, it must go beyond simply making information available. The information should be accessible, intelligible, and perhaps also usable. Transparency could be applied to the substance of the product, service or technology in question – 'what is it?', 'what does it do?', 'how does it do it?', 'how does it interact with me?'. Transparency could also apply to the people and processes around it.

If something is to be trusted then it should be *trustworthy*, for example that trust should not be built on perception alone, it should be grounded in reality. When considering whether a product, service or technology is trustworthy, different standards apply that will reflect its nature. These relate to the impact of the product, service or technology on our lives, either as individuals or as a society. The same standards will not apply to a ballpoint pen as apply to a brain implant; however, whatever the standards that are applied, it is important that the perception of trust is grounded in the reality of something being trustworthy.

Regulation in many ways seeks to build the trustworthiness of those it regulates, using a wide variety of tools that may relate to substance, process and transparency. If trustworthiness is the bedrock of trust, then trusts rests critically on what the regulated firms, and in our case, innovators, do and how they do it. Regulators can enable and encourage, but they cannot deliver trustworthiness themselves.

Recommendation 4: Regulators should consider making explicit statements about the ethical frameworks that guide their decision-making. This should be a matter of routine but is especially important when explaining decisions in sensitive or contentious areas.

Recommendation 5: As part of ensuring such ethical frameworks broadly align with public attitudes, regulators and policymakers should develop tools for broader and deeper stakeholder and public engagement. This could be done through a number of joint projects, in which bodies with similar regulatory issues work together with experts in the field of public engagement to develop and implement a tool kit. Regulators and policymakers should be held to account, including by select committees, for how they develop and implement regulation, including how they engage.

Recommendation 6: Innovators should explicitly adopt a 'responsible innovation' approach, including, for example, signing up to the BSI's responsible innovation standard. Regulators should encourage this in their dialogue with innovators and take it into account when designing and implementing regulation.

Case studies for 'Regulation (and innovation) should embrace ethics and public engagement'

In this segment we have included some case studies that demonstrate positive, negative or unintended consequences of actions when trying to comply with this focal point.

- Academic Health Science Networks (AHSNs) promotion of the adoption of new technologies - Gestational diabetes mellitus (GDm-health)
- Data Ethics Framework
- Introducing a National Innovation Fund and "right to innovate" in Italy
- Public Dialogue on mitochondrial replacement treatment
- Sciencewise Public Dialogue on public views of Modular Nuclear Technologies
- Taiwan Process and digital democracy
- Trust and Ethics, a regulator's perspective: speech by Andrew Bailey, Chief Executive of Financial Conduct Authority (FCA)

Focal point 3: Regulation should take account of commercial considerations and the need to attract investment

Why does this matter for regulation and innovation?

Whether innovation begins with a scientific discovery or technical tinkering, it is critical to understand that there is usually a long and difficult path to it becoming scalable, reliable, affordable and commercial. Therefore, in undertaking our 'deep dive' work, we have been keen not only to understand how new technologies work and what they could achieve, but also to understand the considerations of investors and the critical success factors for their business models.

A key finding is that the enablers of investment and commercial success are not sufficiently understood and considered in the design and implementation of regulation. In our experience, innovators do not see regulation as such as a barrier to scaling up their innovation. Indeed, it is generally understood that regulation exists for a reason, and that the protections it puts in place and the trust it helps to build and maintain, are helpful in creating the conditions for widespread adoption of new technologies. They do, however, report that regulators and policymakers fail to appreciate the cost that regulation entails and especially the implication of those costs on enterprises that may be small in scale and at an early stage of maturity.

We have heard a great deal about the cost associated with delay in regulatory processes, especially where there are regulatory hurdles that must be cleared before a product or process can go to market, for example with licensing or approvals. This was the case in respect of drones, where CAA approval is needed before drones can operate, but where gaining approval has proved time consuming and difficult because it requires data gathered through flying hours. We have also heard, for example, in our fusion energy study, about the negative impact of uncertainty in the regulatory regime, especially when significant investment is about to be made and where investors seek clarity that they will be investing in something that is or can be regulatorily compliant. Several stakeholders have told us that one of the reasons innovative new businesses often sell to a more established player at the point of moving from start up to scale is that the small business is simply unable to cope with the increasing 'overhead' of regulation it experiences during that transition[75].

An improved understanding of the commercial and investor perspective could lead to decisions about regulatory design and implementation that better reflect the full range of

[75] We acknowledge that there are many reasons why start-up firms are often acquired by larger ones, including the desire of larger firms to neutralise potential competitive threats. Some specific examples in the technology sector are set out in an article in the Financial Times by Daniel Thomas, Tim Bradshaw and Nicholas Megaw: 'Why have we not grown any giant companies? The UK's attempt to take on Silicon Valley', 10 September 2021, available at: www.ft.com/content/5466b46d-9cb4-479f-bf5a-1bd15783eb22

costs and benefits. This broader understanding could lead regulators and policymakers to choose different tools, for example so as to reduce the risk that benefits from innovation could be foregone. The 2015 Growth Duty provides guidance that can assist in addressing this point.

What are the biggest gaps and how can they be addressed?

There could be merit in regulators and policymakers building more commercial and investment skills, and experience into their teams. Many of the economic regulators (Ofgem, Ofwat, Ofcom etc) do have 'investor relations' teams today, but much of their time is taken communicating and explaining regulatory decisions, rather than taking soundings to inform them. Unsurprisingly with scarce resource, most of their time is taken up with the larger investors in their sectors rather than engaging with disrupters. Where organisations have boards, the inclusion of those with relevant commercial and investor experience on those boards will bring value (provided that actual and perceived conflicts of interest can be adequately dealt with). Many regulators do have non-executives who bring this experience, but board appointments, and indeed staff appointments, are limited. There may well be a tendency for the pool of those with relevant experience to be dominated by those from more traditional technologies and business models.

We see a strong link between this recommendation and our earlier recommendation on public engagement. Regulators and policymakers will simply never be able to bring into their own organisations the skills and experience needed to enable a good understanding of new technologies and new business models, and their in-house capability will always have to be supplemented by good quality engagement.

One model that could be considered is that of an 'investor panel'. Many regulators in recent times have created 'consumer panels'[76]. These vary in composition, format and in the role, they play in the regulatory process. Some have been required by statute, others set up at the discretion of the regulator. The aim is to ensure that regulators hear the views and experiences of consumers directly, and, over time, to bring the panel members up to speed on regulatory issues and questions such that they can participate in a more informed dialogue than would be possible, say, through a consumer survey or ad hoc focus group. We see merit in a similar approach involving investors. As always, care would need to be taken to ensure the composition of the group included investors in more disruptive technologies and business models as well as established ones. Having an already-established panel, familiarised with regulatory issues to engage in a properly challenging and relevant debate, could make it much easier for regulators and policymakers to include this perspective in their decision-making. It would not be

[76] See, for example, Ofcom's Communications Consumer Panel: www.ofcom.org.uk/about-ofcom/how-ofcom-is-run/committees/communications-consumer-panel or the CAA's consumer panel: www.caa.co.uk/Our-work/About-us/CAA-consumer-panel/ or the Financial Services Consumer Panel, which advises and challenges the FCA: www.fs-cp.org.uk/

necessary for each regulator to establish its own investor panel; indeed, we see merit in creating panels that could be shared between regulators where those regulators had a shared focus (e.g. utilities, life sciences, data science).

Recommendation 7: Regulators should consider establishing an investor panel, which should include investors in disruptive technologies, and which should be used by regulators and policymakers as a sounding board in the development and implementation of regulation

Case studies for ‘Regulation should take account of commercial considerations and the need to attract investment’

In this segment we have included some case studies that demonstrate positive, negative or unintended consequences of actions when trying to comply with this focal point.

- Helping individuals and small businesses access legal support in England and Wales
- Seismic limits on shale gas in UK
- The Investment Industry Regulatory Organisation of Canada’s establishment of an Expert Investor Issues Panel

Focal point 4: Regulatory design and implementation should consider alternatives forms of regulation

Why does this matter for regulation and innovation?

A consistent theme in our discussions of innovation and regulation has been the need for flexibility, adaptability and proportionality. This theme often relates to choices that are made in the design of regulation, in particular the extent to which regulation is ‘rule-setting’ as opposed to ‘goal-setting’ or ‘outcome-setting’. It also – importantly – relates to the form regulation takes, and whether it is set out using legislation or licences, or alternatives such as standards and guidance. There are pros and cons of the different approaches, and we consider them below. We also consider the use of regulatory sandboxes as a useful tool for adaptive regulation.

The merits of alternative forms of regulation

Voluntary, informal or alternatives forms of regulation have several advantages. They can be introduced faster than legislation; they can evolve; they can vary from sector to sector, reflecting different risks or risk appetites; they can allow experimentation; and sanctions can be more flexible. They can not only compliment legislation but also coexist. They can also be much more reasonable in reflecting the spectrum of risk and enabling a proportionate response. The harms for unlicensed vendors, for example, while serious are not equivalent to the existential threat posed by a global pandemic.

Alternatives forms of regulation can also lend itself more to collaborative approaches, where firms and other bodies can agree to redeploy resources across boundaries to allow them to come together to establish standards or norms, and to embed and to disperse them when this has been achieved. This strikes us as a potentially very useful property, given the often boundary-busting nature of technological innovation. It could also reduce the need to create a new regulatory body, which could be inclined to want to look busy and useful by finding itself things to do.

Alternatives forms of regulation can come in several forms.

A less codified, more outcomes-focused approach

The UK legal landscape is a combination of common and statutory law. Codified ‘civil’ law often cannot keep pace with innovation. In “civil code” jurisdictions, and in the UK, in relation to independent statutory regulators, some regulators tend to have limited discretion, being more constrained to act using powers and tools set out in law.

It is, however, inherently true that innovation is highly unpredictable. History is replete with embarrassing quotations from highly intelligent inventors either dismissing imminent

technological improvements as impossible that then rapidly occurred or forecasting spectacular changes that failed to materialise. Even when a new technology comes along, its application can sometimes prove surprising. Under the constraints of a codified 'civil' law system, anticipatory regulation is very hard, if not impossible.

Code-based regulation can become paralysed in an attempt to be exhaustive. This then stifles innovation. This partly explains why some big-data clients of financial firms have moved to the US and cryptocurrency clients to Liechtenstein[77]. No country is perfect and for example, the US has significant disadvantages too, like class action suits, punitive damages, and elected judges, all of which deter innovators.

What are the biggest gaps and how can they be addressed?

We see merit in avoiding the design and implementation of regulation by means of codified civil law approaches where possible. However, there are two main issues[78], that we see with these common law approaches that must be addressed. To note, a completely uncodified approach was described as the "common law approach" by the Taskforce on Innovation, Growth and Regulatory Reform.

The first is an issue of legitimacy. The regulatory regime will only be successful at building and maintaining public trust, which is key for the adoption of new technologies, if it is seen as legitimate. By definition, as the common law evolves by means of precedent-setting decisions, so who makes those decisions matters. There may be some decisions that should be the preserve of Parliament through the legislative process.

In our view, the model of economic regulation, 'UK-style', that accompanied the privatisations in the 1980s and 1990s is a highly successful one and illustrates how this could work. It sees regulators created, with statutory duties, and a set of powers and functions conferred by means of primary legislation. This then gives those regulators a high degree of discretion in when, where and how they use their powers and functions in pursuit of those statutory duties. In our view, this strikes a good balance. These bodies have a degree of democratic legitimacy because of Parliament enacting their statute, which is also reflected in their accountability to Parliament. The discretion they have to act means they can flex their approach according to costs, risks and benefits, which enables them to adapt, including to changes in technology and as society changes over time. Their decisions are challengeable, by means of specialist appeals and judicial review, and these organisations do pay attention towards ensuring their decisions are seen as legitimate, by being authoritative, transparent and consultative.

The second issue with the common law approach, mooted by TIGRR, is a practical one. If the potential for common law approaches to avoid the 'pacing problem' are to be realised,

[77] www.finextra.com/pressarticle/88385/liechtenstein-regulatory-authority-approves-crypto-startup-lirium

[78] We have not expanded on it here but a further issue potentially

those decisions that create the regulatory regime need to be speedy. This should not be in the absence of assessing risks and benefits, as we have discussed in focal point one. This would enable them to adapt in the face of innovative technology, emerging uses or changing societal concerns. The processes that result in them must be accessible and inclusive and their implications need to be communicated effectively. To be clear, if codified ‘hard law’ approaches are dropped and activity is constrained only via litigation, we would not see this as a step in a more innovation-friendly direction. Litigation will always have a role; however, the legal process is too slow and too costly to access. The legal process also results in decisions that are, on their own, too case-specific to be effective as a principal means of regulating. A further issue linked to this point is the lack of enforcement if there is no statutory provision creating an offence or some other mechanism for sanctioning non-compliance. This could lead to regulation being a private law matter between wealthy consumers and businesses, and the onus being on addressing harm done, rather than avoiding harm unnecessarily. This raises further issues on whether that harm can be lived with and rectified and what regulatory uncertainty (pending court views) means for investors and business planning.

This leads us to want to consider other approaches. These include standards, guidance and best practice, which can be used as adjuncts to regulation. They can guide innovators on what they need to do, but also act as pseudo-anticipatory instruments. This can allow innovation to proceed while information is gathered on the need for regulation and as a means of influencing behaviour, such as responsible innovation, which could reduce the need for formal regulation. We also consider regulatory tools that enable experiments and trials, which can help to address pacing issues.

Standards

Standards, certified by industry bodies or by national and international standards bodies (such as BSI and ISO), represent another example of alternative forms of regulation. They are a good example of voluntary agreements to set informal rules that can encourage innovation and benefit customers. It is important to note that standards can be used as a complementary tool that coexist or pave the way for legislation. From screw threads in the 1800s, to electric-plug design in the early 1900s, to shipping containers in the 1960s, to mobile voice and data using 2G, 3G, 4G and 5G in the late 20th and early 21st centuries, the imposition of voluntary standards on industries has been an effective means of opening up vistas of innovation for entrepreneurs.

Where formal regulations give high-level requirements on what is compulsory, standards tell you how to meet your goals and what is best practice. Financial services standards for data encryption clearing are examples of successful standards in the service industry. Banks and insurance companies use standards to manage their supply chain and risks. Setting standards early is usually better than trying to do so late. It is better if companies

developing innovations have clarity on the standards they need to meet, so they can avoid nugatory effort. If an industry standardises too early, however, it can stifle innovation.

Standards can also be a means of achieving international cooperation and common approaches, helping to share best practice across countries and open up markets, which will help the commercial viability and attract investment for technological innovation.

The voluntary approach to standard setting means that standards are developed by those who will use them, and so, they are likely to reflect the considerations of those in the market. Their non-statutory nature, and the fact that they sit beyond public policy, means they are easier to adapt over time.

Standard setting bodies, however, do not have a requirement to operate in the public interests, and their decisions are not subject to the same checks and balances that exist within the legislative process, or which apply to decisions by regulators. There may, therefore, be limits to the types of regulation that society is content to see effectively transferred to these bodies. Further, there is a risk that the standard setting process may become captured if those who volunteer to participate in their development are not balanced across groups with different interests, including those with innovative technologies and business models.

Standards can be incorporated into more formal regulation. For example, regulators might decide to view a company's accreditation under a standards scheme as a useful source of assurance in respect of compliance with their legal obligations. This could be a way of securing the advantages of industry-led approaches, while also ensuring a higher level of checks and balances within the process.

Organisations like the British Standards Institution[79] and the National Physical Laboratory[80] can play a role in facilitating the emergence of standards in industries and we welcome the Government Action Plan on Standards for the Fourth Industrial Revolution[81]. The BSI is working with government and engineers to try get a common baseline for driverless cars[82]. The NPL, which specialises in measurement, has helped hydrogen fuel-cell developers to standardise[83]. The International Organization for Standardization has recently looked at how standards can help innovation for sustainable business[84].

[79] www.bsigroup.com/en-GB/
[80] www.npl.co.uk/
[81] www.gov.uk/government/publications/standards-for-the-fourth-industrial-revolution-action-plan
[82] www.bsigroup.com/en-GB/CAV/
[83] www.npl.co.uk/projects/hydrogen-refuelling-station
[84] www.iso.org/files/live/sites/isoorg/files/store/en/PUB100444.pdf

Regulatory guidance and best practice

Regulators have within their own tool kit the ability to issue guidance and best practice documents. They also delegate such tasks to standards bodies, particularly in providing guidance to firms on how to meet the requirements of legally based regulation. These would not typically confer on the regulator the power to enforce, unlike standards set voluntarily by firms. The regulator could take an active interest in whether firms are operating in line with the guidance and best practice documents, and that could be taken into account in any subsequent enforcement.

A regulator may wish to develop and issue guidance or best practice documents itself rather than pursue a voluntary standards-led approach. For example, if it was concerned that action needed to be taken quickly or if it thought a more industry-led approach could lead to capture by certain interests. Clearly, even in a regulator-led approach, it would still be open to the regulator to follow a more co-creative route, with deep engagement from market participants, including consumers and civil society groups, should it wish. We think this would have the merit of helping to ensure that regulation was grounded in commercial and technological reality, while providing useful process safeguards that would help to avoid capture, maintain checks and balances and create trust.

Regulatory guidance and best practice documents do not have the advantages that come from a voluntary, industry-led approach. They do, however, have similar advantages to standards, described above, in that they are more flexible and easier to adapt over time, which will mean they may well be a more sensible and proportionate responses to technological innovation than a regulatory rush to a new ruleset.

However, there is a risk with regulatory guidance and best practice documents (and indeed with standards, where they are incorporated into a regulatory regime), that these alternative forms of regulatory approaches may harden. This would happen if, for example, the regulator was to interpret guidance and best practice documents as though they were rules, and especially if the regulator were to seek to enforce compliance with them. Guidance and best practice documents, with all the advantages they bring in terms of flexibility and adaptability, are not developed using the same processes or subject to the same rigour and legal challenge as are, for example, licences and legislation. In our view it is therefore unreasonable for regulators to claim the same level of enforceability for guidance, unless the legislation unequivocally says that guidance must be followed. Guidance and best practice documents occupy an important and valuable, place in the regulatory toolkit; they are not a quicker, less onerous route for regulators to introduce enforceable rules.

In the financial services sector, we heard evidence from firms who feel subject to regulation in the form of ‘guidance’ that has not been subject to appropriate cost-benefit analysis (and which may be counter-productive in terms of treating customers fairly).

Furthermore, the risk was highlighted where ‘principles’ which purport to allow flexibility are sometimes treated as hard rules, which therefore raise barriers to entry against small or insurgent firms, but suit those with large balance sheets. For example, retrospective liability may be creating risk aversion, to the extent to which innovative financial products are being developed outside the UK and the system has ‘sucked out the incentive to innovate’. A system comparable to Video Assistant Referee (VAR) in football, where firms can appeal against hardened regulatory ‘guidance’ that they think is damaging to the customer was suggested as an approach going forward.

We recognise the Financial Conduct Authority’s view that is that it is very conscious of striking a ‘Goldilocks’ balance between encouraging innovation and mitigating risk. It is making use of horizon scanning and anticipatory regulatory tools. It told us that it looks to use alternative guidance in the form of speeches, events and workshops to nudge firms in the right direction. Court precedents and judgments often lead to guidance being amended and can therefore act as a middle ground between regulations and its alternatives. The FCA sees guidance as a ‘safe harbour’ in which firms can be confident of not being punished and there is no intention for guidance to become hard law.

There will always be differences in the ways that regulated firms and regulators see the operation of any regulatory regime - But we use this example to illustrate two risks. The first is that, substantively, alternative approaches may harden in ways that undermine their advantages in supporting innovation and undermine the accountability of regulatory decision-making. The second is that, regardless of the reality of how the regulator actually uses these alternative approaches, if there is a *perception* that they are used as hard law, and if firms respond to this perception, the same disadvantages will occur.

Sandboxes

Sandboxes allow controlled experiments in which new products, services, or ways of doing things can be placed into a real-world environment. They have the explicit aim of learning about what happens subsequently to inform the development of future regulatory approaches. They provide valuable lessons for regulators, but also for entrepreneurs and civil society groups. A policy can manifest and develop through stages, with review-points to judge how likely a risk is to crystalise, and this can be an iterative process.

On issues like digital identity, and the use of blockchain in cross-border payments, regulators and industry are learning from sandboxes. Firms say they are glad to have the opportunity; however, a sandbox is not a shortcut, or a route to lower risk tolerance and it must be undertaken within the existing legal framework. We have also heard that caution must be exercised by regulators when setting up and operating sandboxes.

Sandboxes are typically subject to application processes. Not all application processes can succeed, and regulators must take care in how they assess applications, so as not to introduce bias in the selection of sandbox participants. The requirements for entry should

not be unduly onerous, especially for smaller firms or those with different business models. This is important as we heard that participation in a sandbox can confer a competitive advantage. Applications have typically been invited at certain times, and there have been concerns that this could both hold up innovation and favour firms whose innovations are at an appropriate level of maturity at the relevant time. The Kalifa Review of UK Fintech[85] therefore recommended that the FCA move to consider sandbox applications on a rolling basis, which it is doing.

We have also heard that regulatory sandboxes can be good for testing innovative products and services at a small scale, but that some firms would welcome more assistance from regulators as they make the journey to scale. This was also echoed in the Kalifa review, which recommended that the FCA enhance its regulatory sandbox to introduce measures to provide additional support for firms in their growth phase. This is also something the FCA will be implementing[86], with the creation of a 'regulatory nursery' in which the regulator will keep close contact with firms immediately post-authorisation to help steer them in the right direction.

Recommendation 8: We welcome the Government's commitment[87] that regulation will only be considered if necessary, and departments will 'be required to engage with the Alternatives Team in the Better Regulation Executive who will offer support ranging from sign-posting to examples of best practice to bespoke support as needed'. We recommend that standards and other approaches are considered as part of a suite of 'alternatives' and that the Government establish this system where the use of legislation is considered for regulation on an exceptional basis by Winter 2022.

Case studies for 'Regulatory design and implementation should consider alternative forms of regulation'

In this segment we have included some case studies that demonstrate positive, negative or unintended consequences of actions when trying to comply with this focal point.

- Developing performance-based regulations for drones in Rwanda
- FDA adaptation of guidance for doing clinical trials for new antimicrobial drugs
- Setting global standards on smart cities
- Testing smart city technologies in the Republic of Korea

[85] Available at: www.gov.uk/government/publications/the-kalifa-review-of-uk-fintech
[86] www.fca.org.uk/news/speeches/levelling-playing-field-innovation-service-consumers-and-market
[87] www.gov.uk/government/publications/the-benefits-of-brexit

Focal point 5: Regulation needs to get the timing right

Why does this matter for regulation and innovation?

A common theme in many of our discussions with entrepreneurs and innovators has been the importance of timing in regulation. There are risks in regulating early. There are risks in regulating late. Getting it right in absolute terms is likely impossible, and we have heard a great deal about the importance of responsiveness and flexibility, recognising the inevitability of error and the need for change over time.

Together these issues are sometimes referred to as the ‘**pacing problem’**. We unpack each aspect briefly below, and also consider the tools available to regulators and policymakers that could help to improve regulatory pacing.

Don’t regulate too early

There are various reasons why regulating a technological innovation early in its life might be the wrong approach. One is simply the risk that too little is known to make a sensible decision on the most appropriate substance and form of regulation. We discussed earlier in this report the importance of regulation responding proportionately to risk. A reasonable assessment of the nature and scale of future risk may take more data than exist early on in the life of a new technology. The take-up of the innovation may also be so small that the risk is inevitably low at that point. Watching, learning and adapting may well be the right response.

If a decision is made to make regulatory interventions too early, a specific technological approach may be outlawed because it was simply not taken into account, or because beneficial use-cases had not yet been identified. Even if a new technological innovation is *permitted* by regulation, there is a risk of imposing cost at a time when, commercially, the innovator is simply unable to bear it.

Equally, much of the risk that regulation is designed to deal with exists at the interface between a product or a service and the people who work with it, buy it, consume it, or otherwise use it. In the early stages of a technological innovation, it may not be clear what risks it brings. Alongside the risk that early-stage regulation will kill the innovation, comes the risk that early-stage regulation will simply miss many of the issues it should be addressing. It may be better to wait, than to regulate early and then have to make extensive revisions to that regulation.

Unregulated spaces can in themselves enable and prompt innovation, which can in turn be beneficial. An example is vaping, which escaped the tight regulations that covered smoking and so (being at least 95% safer than smoking and used mainly by people trying to quit, according to the Royal College of Physicians), caused significant improvements in

health among smokers, especially in the United Kingdom despite calls for tighter regulation[88]. Regulations to ensure product safety in the UK proved far more effective than regulations to prohibit the practice in the US, India and Australia. Boundaries between regulated and unregulated space, and a desire to be on the unregulated side of the line, can spur 'evasive entrepreneurship', which feeds back to disrupt regulation. For example, Elon Musk's Tesla and others are shaking up regulatory models in the car industry by refusing to join the trade associations of producers.

Don't regulate too late

Regulating too late can also be a problem. If regulation is only imposed after it has become apparent that there is some significant harm in relation to a new technology, there is a risk that trust in that new technology could be significantly undermined. This could lead to a lack of take-up, even after regulation had been introduced, and therefore benefits being foregone. It could also increase the risk of over-burdensome regulation as a response. Furthermore, the absence of regulatory clarity can impact innovative products coming to market as investors may be unwilling to bear the risk that eventual regulation might significantly impact on their product or service coming to market. This is especially pertinent for innovation that have lengthy lead times to come to market and include heavy upfront costs.

For example, on fusion energy, clarity on regulation is an important element to attract investment in new technologies. There was a clear expectation that the technology *would* be regulated, but a lack of clarity on who would regulate it and linked to this, how it would be regulated. This could influence firms' ability to attract investment. The development of the technology had reached a point where further development without greater clarity over regulation created too big a risk that expensive and time-consuming work would later prove to be unnecessary, or of the wrong type, or done in the wrong way.

Regulation can get 'out of sync'

Sometimes, it is not that regulation happens too early or too late, but rather that it has just got 'out of sync' with the real world. Regulation of whatever form – outcome-focused, rules-based, standards-based, guidance – is put in place at a particular time and it is inevitable that things will move on. This can have various negative effects. It results in unregulated new technologies with the risk of hazardous outcomes. Examples include the sale of dangerous hallucinogenic drugs such as LSD in the 1960s or the use of electric scooters today. Conversely, it means that old rules prevent new tools being used, as regulation designed for different technologies prevents innovations being fully realised.

[88] Available at: www.gov.uk/government/news/e-cigarettes-around-95-less-harmful-than-tobacco-estimates-landmark-review

Examples include drones, cryptocurrency, genetic technologies, and new forms of nuclear power.

What are the biggest gaps and how can they be addressed?

Horizon Scanning

It is not clear whether, from a societal perspective, regulating too early is to be preferred to regulating too late or vice versa. We cannot in confidence prefer one error systematically to the other, and anyway, there remains a broader concern about the need for regulation to keep pace with real world developments. So, it is important for regulators and policymakers to consider how regulation might best be done with a view to getting the pacing right – or at least better.

Obviously, regulation stands a better chance of reflecting new developments if regulators and policymakers are aware of those developments. **Horizon scanning** should therefore be an important activity for any regulator. When government is considering regulatory policy or legislation, it is important that they also undertake some horizon scanning. This can provide confidence that the relevant policy or law takes into account future developments, and conscious choices can be made about whether or how regulation should accommodate them. There is clearly a link between good horizon scanning and public engagement, which, when done well would provide useful information about future states of the world and the public response to them.

Of the ten types of horizon-scanning methods that we asked regulators about within our survey, most of the sample indicated that they are currently carrying out nine of them (full results can be found in Annex A). The most common methods used by regulators in our sample are engagement with central government departments and engagement with other regulators[89]. Most, however, described the difficulties in prioritising this activity. Resources are finite and when other issues become priorities, for example in the wake of a safety issue, or consumer protection problem, horizon scanning activity gets dialled down.

We also observed that horizon scanning appears to be work that is undertaken largely in regulatory silos. Each regulator does its own scanning work, which focusses on changes that are relevant to their own areas. The notable exception is the Digital Regulation Cooperation Forum (DRCF)[90] which is a welcome initiative. More regulators ought to explore whether it would be beneficial to undertake more horizon scanning activity jointly across regulators (and possibly with some government departments). This might have the benefit of reducing cost and making it less likely that horizon scanning activity is a casualty

[89] 17 of 18 regulators within the sample.

[90] www.gov.uk/government/collections/the-digital-regulation-cooperation-forum

of other priorities. Furthermore, a great deal of innovation takes place at the boundary between traditionally delineated areas or cuts right across those areas, such as fintech.

The Regulatory Horizons Council undertakes horizon scanning to inform its priorities but rather than undertaking a bespoke horizon scan[91], the Council will be undertaking a 'scan of scans', drawing on existing horizon scanning, and will share our outputs with regulators. We understand the Government Office for Science has cross-cutting expertise on horizon scanning and would encourage that outputs from horizon scanning are not just limited to Government Departments but are also shared with regulators, where appropriate. This includes activities and events like the Emerging Technology Community of Interest and the Heads of Horizons Scanning groups.

Scenario Testing

We have seen some regulators and policymakers making good use of **scenario testing** in developing their regulatory approaches. Within our survey of regulators, most respondents indicated that they use scenario planning to explore alternative ways that a particular policy area might develop in the future[92]. Scenarios are not intended to be predictions. Instead, they identify drivers of change and difference that enable a view to be taken on a range of plausible future states of the world[93]. By constructing several different scenarios, regulators and policymakers can test the robustness of different interventions in a variety of circumstances. It may not be possible or indeed desirable for an intervention to be robust to *all* the future states identified, but it enables conscious choices to be made. It therefore provides a very useful tool when considering the substance, form and timing of regulation in the face of uncertainty.

In some ways the 'pacing problem' is a specific manifestation of the need for a proportionate regulatory response to risk, which we discussed as our first gap. Some of the approaches we have discussed in earlier sections are highly relevant here too. This includes the need for regulators and policymakers to consider the full set of tools in their tool kit, and to attach significant weight to flexibility as a criterion in the choice of tool. The timing of regulation will almost certainly be wrong in some respect. It may be too early or too late, or indeed both, and so the need to choose **regulatory tools that are adaptable** is critically important.

As we have discussed when comparing the use of regulation and alternative approaches above, we see particular pacing risks where regulation is set out in legislation. Formal laws

[91] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/943739/Horizon_scan_background.pdf https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/943740/Horizon_scanning_.xlsm

[92] 12 of 18 regulators in the sample.

[93] The use of scenarios is helpfully and concisely explored in this blog from Nesta: Using scenarios to reimagine our strategic decisions | Nesta

take an increasingly long time to be passed by legislatures and are often then never reformed, despite innovation and new information making them ineffective or counterproductive. A Deloitte study found that 86% of U.S. regulatory codes were changed once or never[94]. This results in the ratchet-like accumulation of regulations, with 'spring cleaning' of such laws being relatively rare[95].

To take a provocative example, lifejackets under the seats of aircraft have hardly ever been used. Flight safety has now reached extraordinarily high levels, while crashes at sea are rarely survivable anyway. It would, however, be a brave politician or regulator who recommended removing them. A less provocative case may be the over-regulation of genetically modified crops in Europe, resulting in the continuation of greater dependence on pesticides in agriculture than would otherwise have been the case, and the refusal to reform this even with the arrival of new ranges of genetic technologies.

We have discussed above the potential for alternative forms of regulation, more adaptive approaches to be effective in achieving regulatory goals. To give a U.S. example, the last four sessions of Congress attempted and failed to bring in formal rules for driverless cars. Yet, the industry needs rules for clarity and legal comfort and alternatives forms to regulation have begun to fill the gap. Various U.S. government agencies and states have promulgated guidelines, standards and voluntary agreements[96]. This is an iterative, adaptive process with 'versions 2.0 and 3.0' coming in successively.

More generally, we heard from Adam Thierer of George Mason University about how, 'set and forget regulation' can hamper innovations, by virtue of its inevitably becoming disconnected from reality. Alternative approaches are useful, but tools such as '**sunset clauses'** have long been advocated as best practice in the UK (for example by the Regulatory Policy Committee). Conventionally, these build into a piece of regulation a date at which the regulation will expire, unless an explicit decision is made (which may be challenged for example by judicial review) to continue it, which would need to include, not only continuing with it as it is, but adapting it to any change in circumstances. Alternatively, other trigger clauses (e.g., relating to market structure or take-up of products) may be included upon which the regulation will automatically expire.

Post-implementation reviews are also useful[97], but this requires a piece of work that, if it is to be done well, will take time and focus. Similar to horizon scanning, there is a significant risk that such work becomes a casualty of other regulatory priorities. We have heard some regulators say that for this reason, they prefer automatic triggers for the expiry

[94] www2.deloitte.com/us/en/pages/public-sector/articles/advanced-analytics-federal-regulatory-reform.html

[95] Adam Thierer: "Evasive Entrepreneurs and the Future of Governance - How Innovation Improves Economies and Governments"

[96] www.dmv.ca.gov/portal/vehicle-industry-services/autonomous-vehicles/

[97] Magenta_Book_supplementary_guide._Guidance_for_Conducting_Regulatory_Post_Implementation_Reviews.pdf (publishing.service.gov.uk)

of regulation. Even if the regulator wishes to retain the regulation, the existence of an automatic trigger for expiry makes it easier to secure the resourcing needed to look at the question. Such triggers therefore help to challenge an inherent bias in any system towards the status quo.

We have also discussed above the usefulness of **sandboxes** in allowing regulators (and innovators) the opportunity to learn together about when and how an innovation should be regulated. There are caveats in terms of how these approaches are best adopted, as we have discussed above, but any regulatory approach that builds in learning and adaptation is a good thing for innovation.

Recommendation 9: Regulators and policymakers should make more use of regulation that is explicitly adaptive, i.e., designed to change over time and avoid rigidity. This includes more use of experimental approaches such as sandboxes and scaleboxes, and also includes greater sharing of information to build best practice in the use of such tools.

Recommendation 10: Horizon scanning for new and emerging technologies is an important tool for addressing the difficult challenges associated with deciding when to regulate. But it tends to be siloed, can be deprioritised and have resource implications; therefore, we recommend that a) Regulators, where appropriate, pool their resources together to conduct horizon scanning and emulate the example of the Digital Regulation Cooperation Forum (DCRF) and b) Government Departments and the Government Office for Science continue to share and expand the reach of horizon scanning outputs and activities on new and emerging technologies with regulators.

Case Studies for 'Regulation needs to get the timing right'

In this segment we have included some case studies that demonstrate positive, negative or unintended consequences of actions when trying to comply with this focal point.

- Ofgem's Innovation Sandbox Service
- Regulation of e-scooters in the UK
- US-Japan Medical Device Harmonisation by Doing (HBD)

Focal point 6: Regulators should foster a culture of openness and a growth mindset

Why does this matter for regulation and innovation?

It is easy to imagine that regulators are monolithic institutions. People often talk about ‘the regulator’ as if it was one individual or at least with a single guiding mind. However, regulators, like all institutions, have their own cultures, which influence what is done and how it is done.

It is important to consider not only the substantive or formal aspects of regulation, but also the people and culture. Indeed, we have found, for example in our work on fusion energy, drones, and genetic technologies, that how people, within regulators, interpret and operationalise the rules is at least as important as what is written in the rule book. We touched on this earlier when we discussed the importance of being clear about the ethical framework that underpins a regulator’s work. Other considerations are important too, and we discuss these below: the skills and experience available to regulators, openness to collaboration and co-creation, and a growth mindset.

What are the biggest gaps and how can they be addressed?

Skills and experience

Regulators are expert bodies. They require a high degree of expertise and wide-ranging competencies to perform their functions and achieve their objectives. All regulators will have people working for them who have amassed considerable knowledge of their area of regulation, which may focus on an industry (such as water, communications, aviation, rail, or energy) or may focus on an issue (such as product safety, food safety or competition and consumer protection). Often regulators find it useful to recruit people from the sectors they regulate, either as staff or on boards. This can be extremely helpful in giving them a perspective on how regulation affects behaviour in firms, as well as technical and operational insights and commercial considerations. The firms they regulate will be keen to invite their regulators to spend time with them and understand more about their world.

Familiarity with the industries or areas they regulate today brings obvious advantages for regulators and should certainly improve the quality of their regulation. Regulators will inevitably be less familiar with new technologies, and so are at risk of regulating in ways that do not appreciate how they work, the conditions that are needed for their economic success, their benefits, or the risks they pose. One of the reasons innovators can find dealing with regulators frustrating is because of this lack of knowledge but – perhaps more so – because the knowledge they do have can give them a particular perspective that makes it harder for the innovator to be heard. Clearly, regulators will find it difficult (and it may be unnecessary) to recruit people with first-hand knowledge of disrupters, but simply

being aware of the issue would help. There are ways for regulators to improve their understanding of technological innovations **by inviting people in to speak and demonstrate, by organising visits and perhaps accepting secondees.**

One area where many regulators are finding it challenging to keep pace of developments is in big data, machine learning and AI. These developments are cross-cutting and have the potential to change many traditionally regulated sectors or areas, creating massive benefits and new risks, but also fundamentally changing the economics and relationships through the value chain. The use of platforms, which bring together different players, coordinating, informing, and learning from multi-lateral interactions over time, has the potential to disrupt many sectors. Most regulators are not expert in the technical or economic aspects of these disruptive technologies. It seems to us that attempts by each regulator to recruit the skills and knowledge it would need to build an appreciation of these new technologies into their work would be unlikely to succeed. Skills and experience in these areas are scarce and highly sought after, and the insight such people would bring would decay over time and would need to be regularly refreshed.

We think it would be sensible to consider developing a way for regulators to access expertise in these areas. This could be achieved by building out the roles of existing bodies such as the Centre for Data Ethics and Innovation[98], the AI Council[99], the Council for Science and Technology[100] or the Data, Technology and Analytics Unit[101], such that they explicitly include a role or objective to aid regulators, if they don't already. The first three of these four bodies do have roles today to provide expertise to *government*, and this will include some regulators that sit within government departments, but it will not include independent regulators. The Data, Technology and Analytics Unit currently sits within the CMA, which is the UK's competition regulator, and this provides a mechanism for cooperating with other regulators and competition authorities though the UK Regulators Network[102] and the UK Competition Network[103], but again, these do not cover all regulators. Any such extension of their roles may need to be supported with resourcing. Our view is that a lot could be achieved by means of the right conversations at the right time, without necessarily creating large additional pulls on resource. This is why we recommended, as part of our report on drones, that the CAA and DMU discuss potential digital markets issues in the roll out and regulation of drones.

See -

98 Centre for Data Ethics and Innovation - GOV.UK (www.gov.uk)

99 AI Council – GOV.UK (www.gov.uk)

100 Council for Science and Technology - GOV.UK (www.gov.uk)

101 www.gov.uk/government/publications/competition-and-markets-authoritys-digital-markets-strategy/the-cmas-digital-markets-strategy-february-2021-refresh

102 Home | UKRN: the UK Regulators Network

103 UK Competition Network - GOV.UK (www.gov.uk)

A further area where competent expertise is scarce and sought-after is public engagement. We noted in an earlier section the importance of public engagement in ensuring that regulation is enabling of innovation in the public interest, for example, the case study (Case Study 18) on Sciencewise's Public Dialogue on public views of Modular Nuclear Technologies.

Good public engagement is not easy to design and implement, and there are experts specifically in this field. There may also be value in regulators undertaking joint work on public engagement in order to identify best practice and gather insight. A panel of experts on public engagement could be established to provide support across regulators, and to help regulators learn from each other in this area. We are aware that bodies such as UK Research and Innovation's funded Sciencewise[104] programme, and Policy Lab in the Cabinet Office can offer formal and informal support across Government, and this could be tapped into by regulators. Public engagement, in this form, will provide a platform to engage on new technology areas and aid in public acceptability whilst informing regulatory and policy development.

Collaboration and co-creation

We believe that if the business of regulation were to become more collaborative and co-creative, regulation would be more enabling and supportive of innovation, and citizens could more easily reach a consensus in their assessment for the use of emerging innovative technologies. Co-creations can lead to innovations such as Etihad Airways' customisable cabin. There appears to us the scope to build on regulators' existing experience to do more here. For example, IKEA launched a digital platform encouraging customers and fans to develop new products[105].

In part, this builds on our earlier observations in this section on the challenges regulators face in accessing the skills and knowledge they need, and the opportunities that collaboration brings to get that access without having to build it into their own organisations. In part, it reflects our view that innovation is happening across the boundaries, between traditionally regulated areas, and in ways that just cut across sectors and change the way value chains work, which demands closer collaboration across those regulatory boundaries. More than this, it reflects the value we place on the collaborative process as creating conditions for fresh thinking and challenge.

Just as collaboration is more than consultation, so co-creation is more than collaboration. In a genuinely co-creative process, people do not simply come together to solve a problem that has already been defined; rather, they work together to define the problem or opportunity, conceptualise a solution and think through how it could be implemented.

[104] Sciencewise supports the commissioning of deliberative dialogue by government bodies to support socially informed and transparent policy making

[105] https://about.ikea.com/en/life-at-home/co-creation

They may even work together to implement it. The process of standards-setting that we described in our section on regulatory and alternative approaches can be a co-creative process.

Regulation is often thought of as an inherently adversarial process, in which the regulator wants firms to do something they do not want to do. This includes imposing rules and monitoring, enforcing and penalising when those rules are broken. While this can and should, from time to time, be the case, we do not see regulation as inevitably working in this way. Regulators are seeking to broadly align the interests of those they regulate with those of society, using a wide variety of tools. Regulated firms – at least those with an eye on their futures – will generally want to gain the trust of the public. This seems to us to be fertile ground for co-creative approaches.

Having identified a broad issue, the regulator could convene a group of relevant stakeholders, including input from experts and members of the public, to help it work out whether there is a problem or an opportunity, what regulation should be seeking to achieve, how it might achieve that, and indeed what others might do[106]. This may reveal scope for the benefits to be achieved without formal regulation, for example through voluntary codes or standards-setting approaches.

The majority of regulators surveyed within our sample agreed that they involve businesses in the co-design of regulations[107]. Clearly, co-creative approaches will not be suitable in all circumstances, and care must be taken to ensure the co-creation group is not captured and the process is fully open.

As we encourage regulators to be more collaborative, we also believe that engagement in International Regulatory Cooperation (IRC) can be a key driver in enabling innovation and scaling it up to reach new markets. Data from our own research emphasised the importance of cross-sectoral collaboration and learning, with all 18 of the regulators in our survey sample stating that they engage with other regulators on an ongoing basis. On the wider stage, we found that the majority[108] of regulators within our survey, work with international partners as part of inclusive and collaborative efforts. The majority of these interactions, however, are limited to knowledge sharing, rather than more ambitious efforts such as joint experimentation or unilateral alignment through 'one-stop shops'.

[106] A useful, and short, analysis of the elements of successful co-creation can be found at: The Co-Creation Imperative: How To Make Organizational Change Collaborative (forbes.com) An example of co-creation in regulation is the Task and Finish Group that Ofwat set up to consider the issues and actions after Ofwat acquired a new statutory duty on resilience in the 2014 Water Act. Its report, which includes more about the composition of the group and its work, can be found at: Resilience Task and Finish Group final report - Ofwat

[107] 12 of 18 regulators in the sample.

[108] 15 of 18 regulators surveyed.

Policymakers and regulators can work with international counterparts and organisations to collaborate on, and learn from, establishing the regulatory frameworks that are fair, transparent and protect citizens and the environment.

Regulators can work with international counterparts to share experience and regulatory insights in highly innovative sectors, and help innovators navigate potential barriers by facilitating cross-border experimentation. An example of where this has worked in practice is within the Agile Nations[109]. Its work programme has ten projects focusing on practical collaboration to share learning and explore new ways to support businesses to introduce and scale innovations across different markets.

Growth mindset and agile approaches

We have noted that regulators are, and must be, expert bodies; however, while expertise is to be valued, some expert cultures can have significant downsides that are not conducive to innovation.

In such expert cultures, there is generally seen to be a 'right answer' or a 'right way', and everything that is not that is wrong. People are valued for knowing the 'right answer' or the 'right way', and challenge or disruption may be dismissed. People in such expert cultures can seek to bolster their perceived expertise by over-complicating things, such that they become difficult for non-experts to engage with.

In recent years there has been massive interest in the work of US psychologist Carol Dweck on 'growth mindset'[110]. Dweck contrasts a 'fixed mindset' and a 'growth mindset'. Broadly, someone with a 'fixed mindset' would believe that they knew how to do certain things and not other things, that they liked to do what they knew how to do and would not enjoy challenges, could fear failure, and believe their capabilities were fixed. By contrast, someone with a 'growth mindset' would believe that challenges provide opportunities to develop, and that failure is an opportunity to learn and grow; they would see feedback as constructive and seek out new things.

Human beings are very susceptible to their environment and so culture is a very powerful determinant of behaviour. It is easy to see how the wrong culture within a regulator, one aligned to a 'fixed mindset', would make it hard for people within the regulator to embrace innovation. Innovation could be seen as a challenge to 'the way we do things around here' and a challenge to the expertise of individuals who have enjoyed status and influence, by virtue of knowing about what they know. This could be as true about innovation in the business of regulation as it is about technological innovation in regulated firms, sectors or

[109] www.gov.uk/government/groups/agile-nations

[110] https://herminiaibarra.com/wp-content/uploads/2019/07/IBARRA_et_al-2018-London_Business_School_Review.pdf

markets. Whatever the substance and form of regulation, if regulators fall victim to a fixed rather than growth mindset, regulation will not embrace innovation.

Agile project management techniques are closely allied to a growth mindset. Originally developed and still mostly used in software development, agile project management involves close collaboration across a team. The overall objective being broken down into chunks, which are worked on in short bursts known as 'sprints'. The goal of each sprint is to do enough to get to the next stage, and at the end of each sprint the team does a 'retrospective' to identify the learning that they will take into the next one. There are lots of agile project management tools and, to the uninitiated, it can feel as much like learning a new language as improving one's project management skills. The essence of agile is that it places a high value on learning, and the tool kit aims to maximise the opportunities for learning throughout delivery. A team may be 'speaking agile' and even 'doing agile' without *being* agile.

Recently, agile project management techniques have broken out of software developers and IT departments and are becoming more mainstream in other types of organisations. They are being used in some areas of policy development[111]. This is precisely because they support an iterative approach, with learning and course correction built in. In our view, there is scope for regulators and policymakers to adopt more agile approaches. We see the potential for these approaches to support more open policy development, giving space for problems to be explored before being defined, and space to discuss alternative approaches. It could be used, for example, as a way of undertaking co-creation. It could also support deeper public engagement. It would also be more likely to help regulators break out of the sort of path dependency that can easily and unintentionally stymie innovation. For example, the FCA have undertaken tech sprints to address specific challenges[112].

The culture and mindset of regulated firms

We have focused above on the importance of a culture of openness and a growth mindset in regulators. It is important to realise that regulation is a function of continuous interactions between regulators and those they regulate. The outcomes that the regulator is seeking to achieve, and which matter to society, are not delivered directly by the regulator but by the regulated firms who respond to the rules, requirements, guidance and expectations that the regulator sets. Similarly, regulators react to the behaviour and performance of the firms they regulate. Intrusive regulatory interventions can be a response to poor behaviour by regulated firms. Everything we have said about the importance of a culture of openness, collaboration and growth mindset therefore applies

[111] An example: Using agile in policy-making - DWP Digital (blog.gov.uk)

[112] www.fca.org.uk/firms/innovation/regtech/techsprints

equally to firms, to innovators and to entrepreneurs as it does to regulators and policymakers.

The corollary of this is that regulators need to ensure that their regulation fosters this culture among those they regulate. This could take the form of lighter touch, potentially more assurance-based, regulatory approaches for firms who display these characteristics. Regulators could make use of participation in standards, for example, as a source of assurance.

Recommendation 11: Regulators should share expertise in key areas such as data, AI and public engagement both domestically and internationally. This could be done by giving existing bodies such as the Centre for Data Ethics and Innovation or UKRI's Sciencewise / PolicyLab an explicit remit to provide such expertise to regulators. Where existing bodies do not exist, this could be done through the formation of a common panel, on which all regulators and regulatory policymakers could draw.

Recommendation 12: Regulators should share their experiences of collaboration and co-creation, with a view to developing their tool kit, so these techniques can be more used both domestically and internationally. The Government (Better Regulation Executive/Brexit Opportunities Unit) should design a regulatory pathway that takes into account not just *what* but also *how* that regulatory intervention has been developed. This includes considering the extent to which regulation has been developed in collaboration, and the way that collaboration has been done (specifically how inclusive it has been beyond incumbents).

Case Studies for 'Regulators should foster a culture of openness and a growth mindset'

In this segment we have included some case studies that demonstrate positive, negative or unintended consequences of actions when trying to comply with this focal point.

- Aviation Industry risk management
- FCA TechSprints
- Policy Hackathon: Realising Smart Regulation in Healthcare
- Regulatory Horizons Council Retrospective August 2019-2020
- The Digital Regulation Cooperation Forum

5. Case studies

In this section, we set out several case studies to bring to life how regulatory principles can enable innovation in practice. In doing so we show how some of the gaps we identify between the aspiration for regulation that enables innovation, and the reality can be closed. In this section we have included some case studies that demonstrate positive, negative or unintended consequences of actions when trying to comply with this focal point.

1) Academic Health Science Networks (AHSNs) promotion of the adoption of new technologies - Gestational diabetes mellitus (GDm-health)

Source: Deloitte report - Medtech and the Internet of Medical Things. How connected medical devices are transforming health care. July 2018[113].

Background: In England, Academic Health Science Networks (AHSNs) were established in 2013 to help the UK government's efforts to develop and spread adoption of innovation across the NHS. This was a network of 15 different regional organisations.

Gestational diabetes mellitus (GDm) affects roughly ten per cent of pregnant women, with an estimated 100,000 women across England impacted annually. Careful monitoring of blood glucose (BG) levels is essential for the successful management of the patients' condition.

What was done: The AHSN network has promoted the adoption of GDm-health™ – a smartphone app that allows the remote monitoring, management and communication between pregnant women with gestational diabetes and health care providers.

The system is comprised of the GDm-health app, which is used with a blood glucose meter by the patient to send real-time patient-annotated BG results via Bluetooth or NFC (near field communication) to a clinical web-dashboard for the care team to see. The web-dashboard enables health care professionals to prioritise care to women most in need and to manage patients in real time through text messages and to communicate with other staff involved in their care. The app makes it possible for women to receive feedback from their care team on their glucose levels and guidance to alter their diet or medication accordingly.

[113] www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-medtech-iomt-brochure.pdf

Result: By March 2017, almost 2,000 women had taken part in the regional pilot, with the results showing a reduction in unnecessary clinic visits by 25 per cent, as well as better glucose control. The system was rolled out to other regions and is part of a five-year strategic research agreement between Drayson Health, the University of Oxford and Oxford University Hospitals NHS Foundation Trust that started in July 2017.

2) Agile governance of self-driving cars in Japan

Sources: WEF agile regulation report 2020[114].

Background: The continuous evolution of automotive technology promises a future in which people do not drive cars – cars drive people. Automotive experts describe a path through which cars progress from having no automation to partial automation (where the vehicle has automated functions like acceleration and steering, but the driver must remain engaged and monitor the environment at all times) and on to full automation (where the vehicle is capable of performing all driving functions in all conditions). However, there are a number of challenges related to the practical applications of this technology, with particular concerns for public safety and accountability when accidents occur.

What was done: To keep pace with technological development, Japan's Ministry of Land, Infrastructure, Transport and Tourism (MLIT) has built an agile regulatory approach. Level 3 autonomous vehicles are now allowed to run on public roads following the revision of the Road Traffic Act in 2020. It includes:

- Using a system of exemptions to permit the trialling of autonomous vehicles that do not meet ordinary regulatory requirements.
- Co-developing voluntary technical requirements with industry for the trialling of autonomous vehicles.
- Adapting technical requirements based on data from trials and with a focus on international harmonization (under UNECE World Forum for Harmonization of Vehicle Regulations – WP29).
- Finalizing requirements once the technology is sufficiently distributed in the market.

Result: MLIT aims to create an outcome-focused, technology-neutral regulatory framework that is predictable and stable, with market surveillance used to balance the need for pre-market testing. It aims to develop the systems needed to conduct such surveillance in real time and ensure the prompt intervention and adaptation of its rules. But to achieve wider autonomous driving, some challenges lie ahead including reaching consensus on the definition of a driver, and who would be responsible if an accident involving an automated vehicle.

[114] www.meti.go.jp/english/press/2021/pdf/0219_004a.pdf

3) Aviation Industry risk management

Sources: Lessons from the aviation industry[115], threat and error management (TEM)[116], CAA threat and error management (TEM)[117].

Background: Flying is often said to be the safest form of transport. Despite huge growth, fatal incidents have fallen every decade since the 1950s. Air accidents peaked in the 1940s, which prompted aviation experts to develop a new safety approach. Aviation has developed standardised methods of investigating, documenting, and disseminating errors and their lessons.

What was done: A "systems approach" was introduced, which conceives error as evidence of systems failure instead of blaming individuals for human errors. Central to this system is the belief that human error is inevitable, and that the purpose of safety systems is to absorb errors.

Threat and error management (TEM) is a safety concept that was developed as a product of collective aviation industry experience. The TEM framework has three basic components:

- Threats: events or errors that occur beyond the influence of the line personnel, increase operational complexity, and which must be managed to maintain the margins of safety**.**
- Errors: actions or inactions by the line personnel that lead to deviations from organisational or operational intentions or expectations**.**
- Undesired states: operational conditions where an unintended situation results in a reduction in margins of safety

Result: Most air traffic accidents still occur because of human error, but safety systems mitigate these errors so that they no longer lead to catastrophic accidents. Aviation is now one of the leading industries in risk management.

[115] https://gisf.ngo/blogs/lessons-from-the-aviation-industry-what-can-we-learn-for-humanitarian-security-risk-management/

[116] https://skybrary.aero/articles/threat-and-error-management-tem

[117] https://www.aviation.govt.nz/assets/safety/human-factors/threat-and-error-management-TEM-awareness-material.pdf

4) Data Ethics Framework

Sources: Data Ethics Framework[118] Updating the Government Data Ethics Framework[119].

Background: The Data Ethics Framework guides appropriate and responsible data use in government and the wider public sector. It helps public servants to understand ethical considerations, address these within their projects, and encourages responsible innovation. It was first published in 2016 and reviewed in 2018. The latest version follows another review in 2020.

It is split into overarching principles and specific actions. These are listed below:

Overarching Principles:

- **Transparency**: Actions, processes and data are made open to inspection by publishing information about the project in a complete, open, understandable, easily accessible, and free format.
- **Accountability:** Effective governance and oversight mechanisms for any project. This means that the public or its representatives are able to exercise effective oversight and control over decisions and actions taken, to guarantee that government initiatives meet their stated objectives and respond to the needs of the communities they are designed to benefit.
- **Fairness:** It is crucial to eliminate the project's potential to have unintended discriminatory effects, and biases which could influence a model's outcome should be mitigated. The project and its outcomes must respect the dignity of individuals, are just, non-discriminatory, consistent with public interest, human rights and democratic values.

Specific Actions:

- Define and understand public benefit and user need.
- Involve diverse expertise.
- Comply with the law.
- Review the quality and limitations of the data.
- Evaluate and consider wider policy implications.

What was done: The data ethics team The consultation on the framework National Data Strategy (NDS) was launched during London Tech Week 2020 to explore whether the strategy appropriately reflected the opportunities and challenges of the digital world and considered all relevant priorities, potential trade-offs and decisions. Following the

[118] www.gov.uk/government/publications/data-ethics-framework

[119] https://dataingovernment.blog.gov.uk/2020/09/22/updating-the-government-data-ethics-framework/

consultation, the Data Ethics team conducted a series of workshops with stakeholders from the public sector, academia, civil society, and industry, where participants applied the Framework to a fictional policy scenario and were asked to identify areas for improvement in practice. Following the workshops, participants were asked to submit further feedback through anonymous forms processed by the team. Updated content was then drafted and tested through five focus groups.

Result: The latest version was updated to include the three overarching principles, and the five specific actions to follow the project process, allowing users to take steps to improve ethical standards of their work involving data. Each action is accompanied by further guidance on how to apply it. A self-scoring system has also been added to help summarise ethical considerations of the project. The principles are scored from 0 to 5 for each project. If a score of 3 or less is achieved in any of the principles, this could indicate the need for additional checks and potential changes to a project to make it more ethical.

5) Developing performance-based regulations for drones in Rwanda

Source: World Economic Forum, Agile Regulation Report 2020[120].

Background: New uses of drone technology offer the potential to transport life-saving supplies, lift people out of gridlock on the roads, and better understand and protect the environment. But in many jurisdictions, drone use is subject to prescriptive aviation regulation, inhibiting use cases that involve drones flying autonomously or beyond the operator's line of sight.

What was done: To unlock the potential of drone technologies, the Rwanda Civil Aviation Authority (RCAA) collaborated with the World Economic Forum to introduce a performance-based regulatory approach. Rather than set prescriptive rules, the RCAA determined acceptable thresholds of risk and required manufacturers and operators to demonstrate how they will meet these performance standards. The regulatory framework enabled any type of drone operation in any location while maintaining safety, a first for drone regulations.

Result: It has enabled new businesses to establish themselves for the delivery of medical products, infrastructure inspections, agricultural and pest spraying, and the surveying of crops and land titling. The initiative has led to the development of a model regulatory framework for drones that can be used in emerging economies.

[120] www.weforum.org/agenda/2019/01/what-the-world-can-learn-from-rwandas-approach-to-drones/

6) EU Directive on End-of-Life Vehicles

Sources: EU rules aim to make the dismantling and recycling of end-of-life vehicles more environmentally friendly[121].

Background: The EU End-of-Life vehicles directive 2000/53, and subsequent regulations were aimed at reduction of waste arising from end-of-life vehicles (ELV). It sets clear targets for ELVs and their components and prohibits the use of hazardous substances when manufacturing new vehicles except in defined exemptions when there are no adequate alternatives.

What was done: The Directive sets clear targets during the lifecycle of a vehicle and treatment options An ELV can no longer be part of the second-hand car market for technical or economic reasons, but it may still have value for its parts. Quantitative targets include:

- Reuse and recycle up to 85% of vehicle weight;
- Reuse and recovery at least 95% of vehicle weight.

Result: This had a significant impact on innovation in the car industry, including, but not limited to:

- Creation of special technical competencies in car manufacturing companies;
- Creation of dismantling & recovery/recycling networks;
- Advances in design for dismantling and recycling;
- Adoption of life-cycle strategies;
- Material regime simplification in cars;
- Material competition and substitution;
- Advances in automotive plastic recycling;
- R&D in innovative recovery technologies for automobile shredding residue (ASR);
- Co-operative research at the industrial level.

[121] https://ec.europa.eu/environment/topics/waste-and-recycling/end-life-vehicles_en

7) EU REACH Regulation

Source: Monitoring the impacts of REACH on innovation, competitiveness and SMEs[122].

Background: The aim of the 2006 EU REACH regulation was to promote innovation in the EU chemical industry and to impose requirements around protection of human health and the environment. It however had negative implications on innovation.

What was done: It imposed heavy testing requirements on all new substances (this was an enormous burden for existing substances) and requirements on testing before bringing substances to market – this reduced the capacity to test for new substances arising from innovation.

Result: The impact on external competitiveness on manufacturers and importers has tended to be negative, due to increased prices related to costs of compliance and increased transaction costs with non-EU suppliers. It was found that investment was shifted away from R&D and channelled into compliance expenditure, and an increase in resources devoted to compliance. Concerns have also been expressed about potential lack of entry of new innovative substances into the EU from non-EU countries due to costs. Increased communication does provide the potential for more innovation in the longer term, but this has yet to be realised.

[122] https://ec.europa.eu/docsroom/documents/14581/attachments/1/translations/en/renditions/pdf

8) FCA TechSprints

Sources: TechSprints, FCA[123]

Relevant focal point: Focal point 6: Regulation should foster a culture of openness and a growth mindset.

Background: TechSprints are events that bring together participants from across and outside the financial services sector to develop technology-based ideas or proof of concepts to address specific industry challenges, traditionally used in software projects.

In 2015, the FCA created a small RegTech team and began to explore the current state of RegTech innovation in the UK, and the challenges of firms involved. They adapted the TechSprint approach and applied it to regulatory issues.

What was done: TechSprints have taken place on multiple topics, including:

- Consumer Access
- Unlocking regulatory reporting
- Financial services and mental health
- Model driven machine executable regulatory reporting
- Pensions
- Global AML and financial crime

As they developed each TechSprint, the FCA refined their model, and have extended the TechSprints over time to include wider events and activities. (expand)

Result: Each TechSprint has brought its own unique elements, but some key outcomes are listed below:

- Profound and rapid learning for regulators, industry and others on the applications and impacts of emerging technologies
- Regulatory interest on issues requiring industry-wide collaboration to progress
- The scale of event impacts beyond the TechSprint: increased regulatory, academic and market focus on the technology or issue
- New partnerships and relationships have been forged and networks have been built across jurisdictions
- Time-bound experimentation has resulted in rapid developments of prototype solutions, and these can be scaled-up and impact the market in time.

[123] www.fca.org.uk/firms/innovation/regtech/techsprints

9) FDA adaptation of guidance for doing clinical trials for new antimicrobial drugs

Sources: Independent review on anti-microbial resistance: regulation of antimicrobial drugs and diagnostics for human and animal diseases main report[124] Independent review on antimicrobial resistance (AMR) Regulation-innovation interactions in the development of antimicrobial drugs and diagnostics: an evaluation of drug and IVD industry views[125].

Background: The FDA has changed guidance for doing clinical trials for new antimicrobial drugs. Regulatory guidelines made clinical trials very difficult, particularly for narrow spectrum drugs. They placed emphasis on experimental purity, meaning that trials were unethical and impractical to run in certain specific indications. For example, former FDA guidance required that no active antibacterial therapy of any kind within 24 hours of enrolment and avoiding the prior use of antibacterial drugs in non-inferiority trials. These guidelines were a major barrier to innovation.

What was done: The FDA have changed their guidance, stating that "a complete ban on all patients who have received prior antibacterial therapy could…have adverse consequences." The industry is now guided towards clinical trials that are more pragmatic. Some statistical hurdles have been lowered, which means trials can be smaller, and more permissive trial recruitment criteria means that it is easier to enrol patients, for example, they changed their guidance to allow for the enrolment of patients who have received up to 24 hours of therapy in the previous 72 hours of enrolment.

Result: This has enabled more rapid and cost-effective development of drugs, and the total R&D cost per drug may have been more than halved as a result of these regulatory adaptations.

[124] www.innogen.ac.uk/sites/default/files/2019-12/Report_AMR_Final_Report_141214.pdf
[125] www.innogen.ac.uk/sites/default/files/2022-02/AMR_Supplement_Industry_View%20_141215-150511r.pdf

10) Forbearance: Ofcom and access prices for final mile fibre

Sources: Promoting competition and investment in fibre networks: Wholesale Fixed Telecoms Market Review 2021-26[126]. Ofcom updates wholesale rules to accelerate the full-fibre rollout[127].

Background: Forbearance is the deliberate and publicly announced decision by a regulator to abstain from intervention. Regulators may wish to forbear in emerging markets where there is a considerable amount of uncertainty, or when it can be expected that the market will become competitive in a short period of time, making regulatory costs from early intervention higher than the potential benefits.

What was done: In the outcome of their Wholesale Fixed Telecoms Market Review 2021-26, Ofcom updated its wholesale rules with the aim of accelerating full-fibre rollout. They decided not to set a price cap on Fibre-to-the-Premises (FTTP) connections, or "full-fibre" as it is commonly known.

Result: Ofcom hopes that this approach will bring benefits to consumers in the long term from innovation, choice, stronger incentives to attract customers through good prices, and a higher quality service, and that it may allow deregulation in other areas. BT's plan to invest £12bn into their FTTP rollout is partly based on Ofcom's direction.

[126] https://acrobat.adobe.com/link/review?uri=urn:aaid:scds:US:92f9b342-b9a5-3a5b-b284-a26bb1804c03

[127] https://telecomstechnews.com/news/2021/mar/18/ofcom-updates-wholesale-rules-accelerate-full-fibre-rollout/

11) Helping individuals and small businesses access legal support in England and Wales

Source: World Economic Forum, Agile Regulation Report 2020[128].

Background: In England and Wales, just one in three individuals – and one in 10 small businesses – with a legal problem got expert advice. Both the public and small businesses cited a number of barriers to using legal services, including price: 63% of people did not believe that professional legal advice was affordable for "ordinary people".

What was done: In response, the Solicitors Regulation Authority worked with innovation foundation Nesta to set up the Legal Access Challenge. This aimed to accelerate the development of products, services and platforms that will help individuals and small and medium-sized enterprises understand and resolve their legal problems with greater ease. In tandem, the regulator wanted to understand whether there were regulatory barriers to mass market legal technology solutions and, if so, how it might adapt its approach.

The regulator succeeded in attracting over 100 entries, often from outside the legal services sector, with coverage in the national media. Following its assessment, the regulator supported eight finalists whose innovations will make legal services more accessible and affordable for individuals, families and small businesses. Backed by a £50,000 grant and an expert support programme, each finalist had six months to develop their solution.

Result: Two winners were announced in April 2020 and were awarded an additional £50,000 prize each to bring their solutions to market. RCJ Advice helps women and children suffering from domestic violence to get legal help to protect themselves from abuse, while Mencap has designed a chatbot to give people with learning disabilities legal advice on care and welfare benefits.

[128] www.publicsectoragility.com/wp-content/uploads/2021/07/WEF_Agile_Regulation_for_the_Fourth_Industrial_Revolution_2020.pdf

12) Introducing a National Innovation Fund and "right to innovate" in Italy

Source: World Economic Forum, Agile Regulation Report 2020[129].

Background: To enable experimentation across the Italian economy, in 2020 the Ministry for Technological Innovation and Digitalization introduced the "Diritto a Innovare", or "Right to Innovate". The legal provision enabled derogations from regulations that inhibit new ideas, products or business models, in order to foster the development, dissemination and use of emerging technologies and high-tech initiatives.

What was done: Innovators – including companies, start-ups, universities and research bodies – that identify a regulatory obstacle are able to ask the government for permission to experiment, through a temporary derogation from statutory regulations. The Ministry evaluates factors including the feasibility of the proposal, the level of technological innovation and its potential economic, social and environmental impact, in conjunction with other relevant authorities. Successful proposals are granted the "right to innovate" for a specified period of time subject to certain conditions.

At the end of the experimentation period, if the trial has been successful, the Ministry evaluates whether and how to introduce revisions to regulations that would enable all businesses to benefit from the same rules.

Result: A similar approach to experimentation has been introduced in Japan and the UAE[130], while, in Germany, experimentation clauses have been introduced to enable experimentation in energy, media and transport. The 2019 index published by the World Bank ranks Italy as 51st on a list of countries which favour entrepreneurship.

[129] www.mise.gov.it/index.php/en/202-news-english/2039363-the-national-innovation-fund-unveiled
[130] https://reglab.gov.ae/

13) Ofgem's Innovation Sandbox Service

Sources: Ofgem Innovation Sandbox Service[131].

Background: Ofgem launched a regulatory sandbox to experiment with ways of mitigating barriers when an innovator's plans do not fit readily within the rulebook but where there was a prospects of consumer benefit. The sandbox service aims to help innovators that would like to offer something different to energy consumers and can support them in delivering trials or entering the market with a new product or service.

What was done: Ofgem launched the regulatory sandbox service in 2017, and they have now run two windows. The first window was launched in February 2017 and the second in October 2017, and they received 67 expressions of interest across the two windows. They found that many innovators required support to better understand the rules of the energy sector, and in most cases provided feedback on how these innovators could go ahead without a sandbox. Three sandboxes were enabled during the first window and four in the second window. Through both windows, Ofgem gained insights and found ways to evolve their service:

- It is not always clear to innovators what they can and cannot do, and innovators commonly need advice, not a sandbox;
- When a proposition is not possible today it is usually due to a complex mix of requirements including industry norms, systems, codes, charging arrangements and licences;
- Innovators are focused on launching businesses, not trials;
- Start-ups want to signal low regulatory risk to investors;
- Innovators must operate within existing structures;
- Innovation is happening across the sector, with local energy supply and trading featuring strongly.

Result: Ofgem adapted their service to allow innovators to access the sandbox at the time of need, creating an on-demand service which means that the stage of development determines timing of requests, and innovators do not feel forced to ask for support too soon. As a result, Sandbox 2.0 was launched in July 2020 and is an open access service without any deadlines.

[131] www.ofgem.gov.uk/publications/innovation-sandbox-service-overview

14) Policy Hackathon: Realising Smart Regulation in Healthcare

Sources: Imperial researchers inform smarter regulation in healthcare at policy hackathon[132].

Background: Academics from Imperial College London joined a leading group of experts including healthcare regulators, NHS leaders, statutory bodies and policymakers for a virtual policy hackathon organised by The Forum[133] and the think tank Reform[134] on "Realising Smart Regulation in Healthcare." They discussed factors that stifle innovation, and how they can be addressed.

The hackathon built upon previous research Reform produced in collaboration with NHSX, which identified the main points of tension in the regulatory process for innovations in data-driven healthcare.

What was done: In the hackathon, questions and problems from Reforms research were explored, and attendees were split into groups with a moderator. The aim was to come out with practical steps and solutions on aspects of the current regulatory pathway for data-driven technologies in healthcare -

- Data access
- Proof of concept and evidence building
- CE marking and post-market surveillance
- Overall regulatory processes

Result: A post-event write-up[135] has been produced, which has been put forward to provide potential policy solutions to the tension points.

[132] www.imperial.ac.uk/news/200433/imperial-researchers-inform-smarter-regulation-healthcare/
[133] www.imperial.ac.uk/the-forum
[134] https://reform.uk/who-we-are
[135] https://reform.uk/research/realising-smart-regulation-healthcare

15) Public dialogue on mitochondrial replacement treatment

Sources: White Paper on Fourth Industrial Revolution[136].

Background: Unhealthy mitochondria can cause genetic disorders (mitochondrial disease), which can lead to a range of conditions including deafness, blindness, diabetes and heart and liver failure and can have devastating effects on families that carry them. For many people with mitochondrial disease, preventing transmission to children is of concern. Mitochondrial replacement treatment focusses on replacing or reducing the effects of these mutations in mitochondria and can help women prevent the transmission of mitochondrial diseases to their children.

What was done: In 2012, the Human Fertilisation and Embryology Authority undertook engagement to understand public acceptability of the use of mitochondrial replacement treatment, including workshops, a public survey, open meetings and focus groups, and trusted scientific figures were invited to take part in the debate. It was found that there was general support for permitting mitochondria replacement in the UK, providing it is safe enough to offer in a treatment setting and within a regulatory framework.

Result: Following legislation the UK became the first country in the world to licence mitochondrial donation techniques in 2017, allowing women who carry a risk of serious mitochondrial disease to avoid passing it onto their children.

[136] www.gov.uk/government/publications/regulation-for-the-fourth-industrial-revolution

16) Regulation of e-Scooters

Sources: Regulating electric scooters (e-scooters)[137] Illegal use of private e-scooters on the rise[138].

Background: e-Scooters could play a part in addressing urban transport challenges such as poor air quality and increased congestion. However, they are currently banned from UK roads and pavements.

What was done: It is legal to buy and sell e-scooters privately, however it is illegal to ride them on public roads, pavements and cycle lanes, owners can ride them on private land with the owner's permission. E-scooters are classed as motor vehicles as defined by Section 185 of the Road Traffic Act 1988. All motor vehicles must have certain characteristics, including, tax, MOT, lights, number plates, but e-scooters do not meet these requirements. This means that riders could face a £300 fine and six points on their licence if they use them on public roads or pavements. However, their popularity is increasing. In November 2020 for example, retailer Halfords reported a 71% rise in sales of e-scooters after the announcement of the second lockdown[139]. In London, the Metropolitan Police has seized more than 3,600 privately owned e-scooters in 2021[140]. Between January and June 2021, 258 collisions involving e-scooters were also recorded.

Result: The Government is considering whether the law should be changed. As part of this consideration, the Department for Transport introduced legislation in July 2020 to enable rental e-scooter trials to take place on public roads and cycle lanes across the UK. The Government is awaiting the outcome of these trials before making a decision on whether to change the law. The trial has been extended until Spring 2022.

[137] https://commonslibrary.parliament.uk/research-briefings/cbp-8958/
[138] https://roadsafetygb.org.uk/news/illegal-use-of-private-e-scooters-an-issue-on-the-rise/
[139] https://www.bbc.co.uk/news/uk-england-london-55644560
[140] https://www.bbc.co.uk/news/uk-england-london-59912332

17) Regulatory Horizons Council Retrospective August 2019-2020

Sources: RHC Team Retrospective, August 2020[141].

Relevant focal point: Focal point 6: Regulation should foster a culture of openness and a growth mindset.

Background: Retrospectives are meetings held by a team after the end of a project or a significant period of activity. As a relatively new organisation the RHC recognised that learning and adapting are key pillars to success. This was the team's first retrospective, covering the period from August 2019 to August 2020. Nine team members attended the workshop, facilitated using an interactive whiteboard.

What was done: The team noted all key activities of the RHC over the time period, and placed them into one of four quadrants: went well, we learned, differently, puzzles us. The team then identified activities from the "Differently," or "Puzzled Us" quadrants that they felt were the most important, and then picked a specific challenge and developed an action plan for the coming phase of work.

Result: The "Went Well" quadrant was the most populated, including activities involving collaboration and engagement across the team, which was identified as a way the team works particularly well. There were several key learnings under the "We Learnt" quadrant, as a new organisation, with several activities relating to the team's approach and methodology for selecting priorities. The "Do Differently" quadrant included adapting to unforeseen circumstances where the team had to adapt, including policy developments, and adapting to Covid-19, including important lessons for making the team's approach more resilient. In the "Puzzles Us" quadrant, the most substantive questions were around methodology.

The team then identified things they could do to address these, including having more detailed discussions on the areas around methodology, recognising the challenges, a strategy moving forwards and next steps. This exercise showed a growth mindset and a culture of continuous learning in the Council.

[141] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/943738/RHC_team_retrospective.pdf

18) Sciencewise's Public Dialogue on public views of Modular Nuclear Technologies

Sources: Public dialogue commences on public views of Modular Nuclear Technologies[142] Public dialogue on Advanced Nuclear Technologies (ANTs)[143].

Background: The Department for Business, Energy and Industrial Strategy (BEIS) is undertaking a dialogue, co-funded by UK Research and Innovation's Sciencewise Programme, to further understand public insights and expectations around the potential future siting and deployment of modular nuclear technologies in the UK. BEIS has partnered up with the Welsh Government, National Nuclear Laboratory (NNL), the Office for Nuclear Regulation (ONR), the Environment Agency (EA), the Nuclear Innovation and Research Office (NIRO) and Natural Resource Wales (NRW) to ensure that the dialogue informs as many interested parties as possible. This dialogue was among the first in the UK specifically on advanced nuclear technologies, and therefore aimed to explore a broad range of issues to provide insight into priority themes for future engagement. The dialogue set out to draw conclusions based on an understanding of the following research questions:

- What are participants' perceptions, hopes and concerns about the development and use of advanced nuclear technologies?
- What influences those views of advanced nuclear technologies and, given that, what might make participants more or less open to the use of them?
- What do participants think is important when considering how advanced nuclear technologies might be sited and how to use advanced nuclear technologies?

What was done: The dialogue was initially designed to be held face-to-face, but the approach changed due to the Covid-19 pandemic, and the dialogue was delivered online, including six Zoom workshops and activities on Recollective, a digital engagement platform.

The dialogue had three phases, to build toward deliberating advanced nuclear and it stayed relatively high-level on these topics. Facilitators reflected on emerging views after each workshop, and after the final workshop, the data and emerging themes were used to develop early findings to share with participants. All qualitative data was then thematically coded for robust and neutral analysis.

[142] https://sciencewise.org.uk/2020/12/public-dialogue-commences-on-public-views-of-modular-nuclear-technologies/

[143] www.gov.uk/government/publications/public-dialogue-on-advanced-nuclear-technologies-ants

Result: The views of participants were found to be complex and nuanced, and grounded in perspectives on achieving net zero, current nuclear energy, and the information provided within the dialogue. Some key findings include:

- Participants were generally surprised to learn that nuclear is a low-carbon form of energy and did not realise that it could play a role in reaching net-zero. This framing therefore played a key role in shaping their views throughout the dialogue.
- Participants had greater concerns for the deployment of advanced nuclear technologies than hopes.
- Overall, the number of participants willing to consider deploying advanced nuclear technologies to support reaching net-zero increased over the dialogue, and by the end a majority were willing to consider it, with a number of conditions: a robust need case, renewable energy being central to achieving net zero, health and safety must be prioritized, no long-term risks or a negative legacy, robust and independent regulation.
- Public engagement is essential.

Due to the deliberative nature of the engagement, participants had the opportunity to learn about the topic further and reflect on this, and hear views different to their own, therefore their views may change throughout the process. The study found that interactions with specialists, particularly specialising in safety and regulation of nuclear energy, had the most impact on the views of participants.

The outputs from this dialogue will inform future policy development and engagement with the public. The study recommended that additional in-depth engagement would be beneficial following further research and development of the technologies.

19) Seismic limits on Shale Gas in UK

Sources: Could seismic limits mean INEOS steps away from UK fracking[144] Concreating up Britain's only shale gas wells[145] UK's Cuadrilla still plans to plug shale gas wells as mandated[146].

Background: Seismic limits on fracking may mean that companies move operations away from the UK.

What was done: Current law states that companies must stop work if they trigger earth tremors of 0.5 or more on the Richter scale. If this limit is passed, any operations and tests must be suspended. Companies such as INEOS and Cuadrilla have called for rules on shale gas to be relaxed. INEOS has hinted that they are unlikely to apply for consents to undertake fracking if these limits are not reviewed, and that they feel that the industry is being stopped from moving forward.

Result: Cuadrilla plans to plug the country's only two viable gas wells later this year.

[144] www.futurenetzero.com/2019/04/16/could-seismic-limits-mean-ineos-steps-away-from-uk-fracking/
[145] https://cuadrillaresources.uk/6205-2/
[146] www.reuters.com/business/energy/uks-cuadrilla-still-plans-plug-shale-gas-wells-mandated-2022-03-09/

20) Setting global standards on smart cities

Sources: White Paper on Fourth Industrial Revolution[147].

Background: Many cities face challenges in ensuring sustainable growth, with issues ranging from provision of water and energy to management of healthcare and transport. A range of innovation is emerging to create the smart cities of the future. The British Standards Institution has developed a ground-breaking series of standards on smart cities, in collaboration with the Future Cities Catapult.

What was done: ISO standard 37106 helps cities deliver their vision for a sustainable future. Published in August 2018, following a five-year process of research and engagement with city leaders, ISO 37106:

- Defines a smart operating model for cities, which enables them to operationalize their vision, strategy, and policies at a faster pace, with greater agility and with lower delivery risk.
- Provides a toolkit of smart practices for managing governance, services, data and systems across the city in an open, collaborative, citizen-centric and digitally enabled way.

Result: International recognition of the smart cities standards programme contributes to the UK's reputation in advanced urban services and helps shape the global market in line with established UK good practice. Downloaded in over 60 countries, UK smart city standards are being adopted as international standards. Key benefits that users report include:

- Holistic nature of the standard
- Citizen-centric approach
- Addresses the organizational barriers to getting real benefit out of city data and smart technologies
- Highly supportive of the city's local strategy
- Not a one-size-fits all approach,
- Flexible to meet local needs
- Provides a common framework for action across multiple city stakeholders
- Modular and pragmatic structure of ISO 37106 means cities can choose where to start, then implement further aspects of the standard over time
- Reduces risk

In China, the world's largest smart cities market, the British Standards Institution has set up a cooperation agreement on smart cities with the Standards Administration of China to

[147] www.gov.uk/government/publications/regulation-for-the-fourth-industrial-revolution

develop a common approach to smart cities between UK and Chinese cities and companies.

21) Testing smart city technologies in the Republic of Korea

Sources: Smart Cities South Korea market intelligence report[148] The new smart city act will come into effect on the 17th [149] WEF agile regulation report 2020.

Background: The Republic of Korea is pioneering the development of smart city technologies to make city life more sustainable, improve citizens' quality of life and support the development of new industries. The Korean Government has realised that regulatory reform is required to allow for the commercialisation of smart technologies, and they are moving towards a negative-listing regulatory approach for technologies surrounding the fourth industrial revolution. This means that new business models and solutions are considered legal unless explicitly prohibited by law.

What was done: The Special Act on Promotion and Vitalization of Convergence of Information and Communications Technology (2018) lifts regulations for a limited period in strategic growth industries that are related to ICT (Information and Communications Technology), and the regulatory sandbox applies to all designated smart city projects. The sandboxes allow pilot projects to occur free of regulations in limited geographical areas. These regulatory exemptions are awarded on a project basis, covering six categories: personal data usage, autonomous vehicles, drones, private networks, software development and land use. Regulatory exemptions are subject to committee review and local consultation and may be granted for a period of up to six years. Following local trials, decisions are taken about how to adapt regulation in other regions or more generally nationwide.

Result: A total of twenty-five cases have been approved, including autonomous driving security robots, route guidance platforms for visually impaired people, safety services that use unmanned drones, and a demand-response bus, which changes routes in real time according to demand of passengers, using an app and an AI algorithm to determine the best route, which reduces the average waiting time of citizens by 70% and travel time by 40%.

[148] https://documentcloud.adobe.com/link/review?uri=urn:aaid:scds:US:e33a2b30-6d7f-406f-a748-4b67ea2f5bf5

[149] https://smartcity.go.kr/en/2021/06/16/17%EC%9D%BC%EB%B6%80%ED%84%B0-%EC%83%88%EB%A1%9C%EC%9A%B4-%EC%8A%A4%EB%A7%88%ED%8A%B8%EB%8F%84%EC%8B%9C%EB%B2%95%EC%9D%B4-%EC%8B%9C%ED%96%89%EB%90%A9%EB%8B%88%EB%8B%A4/

22) The Digital Regulation Cooperation Forum

Sources: The Digital Regulation Cooperation Forum[150].

Background: The Competition and Markets Authority (CMA), the Information Commissioners Office (ICO) and the Office of Communications (Ofcom) formed the Digital Regulation Cooperation Forum (DRCF) in July 2020.

The DCRF was established to ensure a greater level of cooperation, given the unique challenges posed by regulation of online platforms.

What was done: The DRCF has the following six objectives:

- Objective 1: Collaborate to advance a coherent regulatory approach by facilitating open dialogue and joint working to ensure that regulation and other enforcement tools applied to the digital landscape are developed and implemented in a coherent way, and produce effective and efficient outcomes that maximise benefits for consumers across policy areas.
- Objective 2: Inform regulatory policy making by using the collective expertise of the Forum to explore emerging policy challenges in the digital space and develop solutions to inform regulatory approaches.
- Objective 3: Enhance regulatory capabilities by pooling knowledge and resources to ensure that all members have the skills, expertise and tools needed to carry out their functions effectively in digital markets.
- Objective 4: Anticipate future developments by developing a shared understanding of emerging digital trends, to enhance regulator effectiveness and inform strategy.
- Objective 5: Promote innovation by sharing knowledge and experience, including regarding innovation in the approaches of regulators.
- Objective 6: Strengthen international engagement with regulatory bodies to exchange information and share best practice regarding approaches to the regulation of digital markets.

Result:

Since their launch, the DRCF has released its Workplan for 2021/22, setting out a roadmap for increasing its scope and scale of co-operation. The roadmap focusses on three priority areas:

- Responding strategically to industry and technological developments
- Developing joined-up regulatory approaches

[150] www.gov.uk/government/collections/the-digital-regulation-cooperation-forum

- Building shared skills and capabilities

They have also released further publications, including:

- Embedding coherence and cooperation in the fabric of digital regulators: a summary of ideas to address barriers to cooperation and measures to strengthen digital regulatory cooperation in future.[151]
- CMA and ICO joint statement on competition and data protection law[152]
- Joining up on future technologies: a technology horizon scanning programme, to provide a coherent view of new and emerging digital markets and technologies[153]

The Financial Conduct Authority (FCA) has also joined as a full member in April 2021.

[151] www.gov.uk/government/publications/digital-regulation-cooperation-forum-embedding-coherence-and-cooperation-in-the-fabric-of-digital-regulators

[152] www.gov.uk/government/publications/cma-ico-joint-statement-on-competition-and-data-protection-law

[153] www.gov.uk/government/publications/joining-up-on-future-technologies-digital-regulation-cooperation-forum-technology-horizon-scanning-programme

23) The Investment Industry Regulatory Organisation of Canada's establishment of Expert Investor Issues Panel

Source: Regulator asks for input on composition of new investor panel[154].

Background: The Investment Industry Regulatory Organisation of Canada (IIROC) is establishing an Expert Investor Issues Panel (EEIP) aimed at adding ongoing investor input into the IIROC's regulatory activities.

What was done: IIROC has conducted retail investor research since 2017 using an investor panel made up of 10,000 individuals, completing several surveys on topics such as access to financial advice, protecting vulnerable investors, and more generally on awareness, understanding and perception regarding regulation of the investment industry.

IIROC is conducting qualitative research with investors who have complained directly to them, to gain better insight into their experiences of the complaint-handling process, and to help them better navigate the regulatory system. IIROC is also seeking views of the public on how the new EIIP should be composed, selection processes for input, term limits, and its governance.

Result: By creating a pan-Canadian investor-focused panel, IIROC aims to further enhance investor outreach efforts and serve as an additional forum that will provide a strong voice for investors and help IIROC accomplish its goal of investor protection.

[154] https://insurance-portal.ca/economy/regulator-asks-for-input-on-composition-of-new-investor-panel/

24) Trust and ethics, a regulator's perspective: Speech by Andrew Bailey, Chief Executive of the Financial Conduct Authority (FCA)

Andrew Bailey delivered a speech at the launch of the St Mary's University School of Business and Society on 16th of October 2018[155], where he discussed trust and ethics, reflecting on the financial crisis, and steps forward.

Reflecting on the financial crisis, he stated that, "in financial services, it was evident in the advocacy of light touch regulation, the view that left to themselves firms would succeed," but "it didn't work out that way, and in the wake of the crisis we have had to change the approach to regulation in the public interest."

He highlighted the introduction of the Senior Managers and Certification Regime following the work of the Parliamentary Commission on Banking Standards, and the concepts of responsibility and accountability at the heart of this, stating that, "these principles are at the heart of rebuilding trust." He also highlighted the FCA's work on the culture of firms that they regulate, and stated, "it is not just for the regulator to pursue these objectives. Critically, and primarily, they have to be internalised by firms and their staff."

He concluded with, "we are not at the end of this journey, and arguably never will be. In the end, neither the economist, the philosopher and phycologist is correct on their own. And yes, the lawyer and the regulator have a bit of a role to play."

Key highlights form the speech are listed below:

- The financial crisis of a decade ago, and the subsequent revealing of serious conduct problems in too many areas of financial services has without doubt severely damaged any sense of trust.
- Trust has a moral and ethical dimension to it, and it involves commitment.
- My (Andrew Bailey's) view is that trust in finance has changed over time.

[155] www.fca.org.uk/news/speeches/andrew-bailey-trust-ethics-regulators-perspective

25) US-Japan Medical Device Harmonisation by Doing (HBD)

Source: US/Japan Regulatory Collaboration[156].

Background: Regulatory frameworks can differ across countries and cultures. International collaboration therefore plays an important role in meeting the challenge of emerging technologies and globalisation. Through the US-Japan Medical Device Harmonisation by Doing (HBD), the FDA, Japanese regulators, academia and industry developed internationally agreed upon standards for global clinical trials related to cardiovascular devices and addressed regulatory barriers that could delay approvals in both countries.

What was done: Since the first meeting in 2003, a series of think-tank type meetings have been held, and a working group has been established. HBD undertakes several activities, including:

- Scientific Sessions: HBD organises scientific sessions along with annual conferences to promote regulatory convergence and to discuss advances in cardiovascular technology;
- Global Cardiovascular Device Clinical Trials: HBD has a workgroup focussed on moving Japanese and US clinical study sponsors and regulators to the use of a single clinical trial protocol rather than parallel country-specific ones, meaning that the US could accept data from Japanese clinical studies and vice versa;
- Registries: HBD has a workgroup focussed on standardising information available in post market data registries and reducing manufacturers' premarket data requirements by using post market data. The workgroup is developing an International Consortium of Cardiovascular Registries to bring together registry information from multiple countries.

Result: Some examples of products approved by FDA and PMDA via the HBD pathway include:

- Cook Ireland's Zilver PTX drug-eluding peripheral stent, approved in November 2012;
- Terumo Medical Corporation's Misago peripheral elf-expanding stent system, approved in May 2015;
- Cardiovascular Systems' orbital atherectomy system (OAS), approved in March 2017;
- Medtronic's Harmony Transcatheter pulmonary valve, approved in March 2021.

[156] www.fda.gov/medical-devices/cdrh-international-programs/usjapan-regulatory-collaboration

26) Taiwan Process and digital democracy

Source: Anticipatory regulation: 10 ways governments can better keep up with fast-changing industries[157] vTaiwan[158] Digital democracy: the tools transforming political engagement[159].

Background: A practical challenge for regulators is stakeholder interactions. Attempting to bypass public engagement can be one of the biggest risks for industries, given the huge implications and ethical issues surrounding emerging technologies. The vTaiwan process was established by a civil society movement called g0v, at the invitation by the Taiwanese Minister for Digital Affairs. It followed g0v's major role in the 2014 Sunflower Movement protests; started over a controversial trade agreement with China.

What was done: Designed to be a neutral platform to engage experts and relevant members of the public in large-scale deliberation on specific topics, the vTaiwan process aims to facilitate constructive conversation and consensus building between diverse opinion groups. It consists of several stages including an initial Objective stage for crowdsourcing evidence, and a Reflective stage using the mass deliberation tool Pol.is, which helps to form a rough consensus. The final stage involves key stakeholders being invited to a live-streamed, face-to-face meeting to draw up recommendations. Facilitators including Government volunteers guide people through the stages using different web-based tools such as emails, timelines and access to clear information. The entire consultation is continuously summarised, transcribed and then published in an open, structured and searchable format.

Result: vTaiwan has several notable achievements, including: a crowdsourced bill successfully passed through Parliament on Closely Held Company Law; the ratification of several items on ridesharing (Uber) regulations; and the resolution of a disagreement between civil society activists on the topic of internet alcohol sales.

[157] www.nesta.org.uk/blog/anticipatory-regulation-10-ways-governments-can-better-keep-up-with-fast-changing-industries/

[158] www.nesta.org.uk/feature/six-pioneers-digital-democracy/vtaiwan/

[159] www.nesta.org.uk/report/digital-democracy-the-tools-transforming-political-engagement/

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