REGULATORY HORIZONS COUNCIL

The Role of Regulation in Supporting Scaling-up

January 2024

Contents

Introduction

The Regulatory Horizons Council (RHC) is an independent expert committee sponsored by the Department for Science, Innovation, and Technology (DSIT). The Council identifies the implications of technological innovation, and provides government with impartial, expert advice on the regulatory reform required to support its rapid and safe introduction.[1] It has so far published reports on innovations including (but not limited to) drones, artificial intelligence (AI) as a medical device, and genetic technologies.

In June 2022, the Council published its first cross-cutting report: *Closing the Gap Between Regulatory Principles and Practices.*[2] This report outlined a number of practical solutions that regulators, policymakers and industry can use to put widely recognised pro-innovation regulatory principles into practice. The report also acknowledged that there is more to be done to understand and create a regulatory system that allows innovation to flourish. Since then, the Council has initiated a number of short policy sprints, convening regulators, innovators and policymakers to further develop key themes identified in the report.

One such theme identified was the disproportionate effect of regulation on smaller businesses such as start-ups and scaleups[3], and its influence on the ability of companies to scale and grow further. The UK has a distinguishably strong research and development (R&D) reputation and start-up community, but has faced challenges in scaling innovations on UK shores. Regulation, whilst only part of the issue, will play a large role in determining the future success of UK start-ups and scaleups, and we believe it has been an overlooked part of the policy ecosystem. This short project explored how regulation can better support and enable this innovative fraction of the UK's industry ecosystem to scale their businesses. The report retains the practical approach of the *Closing the Gap* report, with a focus on showcasing examples of existing good practice.

[1] For further information, see: https://www.gov.uk/government/groups/regulatory-horizons-council-rhc

[2] Regulatory Horizons Council (2022): Closing the Gap Between Regulatory Principles and Practices. Available at: https://www.gov.uk/government/publications/closing-the-gap-getting-from-principles-to-practice-for-innovation-friendly-regulation

[3] There are many existing definitions of start-ups and scaleups. We are defining start-ups as new businesses that are seeking to bring a unique product or service to market. Scaleups have been defined by the OECD as firms growing their employment numbers and/or turnover by more than 20% a year over a period of three years, with at least 10 employees at the start of the period. OECD/Eurostat (2008), Eurostat-OECD Manual on Business Demography Statistics, OECD Publishing, Paris, https://doi.org/10.1787/9789264041882-en.

Why should the UK support small businesses to scale?

Now is a crucial time for the UK to support the start-up and scaleup community to further scale for many reasons. Firstly, UK economic productivity growth is slowing down, and is lower than comparable countries such as France, Germany and the US.[4] Secondly, the UK (and the world) is grappling with a number of challenges, such as strained health systems, ageing populations and climate change. Start-ups, by their disruptive nature and ability to take on more risks, will play a vital role in supporting the transformative innovation needed across sectors to deal with these, and many more, challenges.

Supported by a world-class R&D base, the UK already has a thriving community of start-ups and scaleups. The Centre for Entrepreneurs' most recent Business Startup Index (based on Companies House data) found that even despite the shock of the pandemic, business formations reached a new record of 790,390 in 2022, growing 4.53% since 2021.[5] Moving beyond business conception, scaleups also play a vital role in the innovation ecosystem. The Scaleup Institute's 2022 Annual Review found that in 2020, the 33,995 scaleups in the UK represented over 50% of the total Small and Medium-sized Enterprises (SME) turnover output despite making up less than 0.6% of the SME population, employed over 3 million people, and generated £1.2 trillion for the UK economy. They were also on average 42% more productive than other firms in the same sector.[6]

However, despite these promising statistics, there are reasons why we should be concerned about the fate of smaller businesses in the UK. Start-ups and scaleups being able to further scale commercially is fundamental for leveraging their full economic potential, as a 2017 House of Lords report on the life sciences sector notes, "the real economic value comes not from funding start-ups but from enabling scale-up".[7] It has been recognised that UK start-ups across a range of sectors are struggling to reach commercial scale, and when they do are being merged into international corporations.[8, 9] Further, before even reaching this stage there are signs that companies are moving their operations offshore as they grow - between 2015 and 2020, London accounted for only

[4] John Van Reenen (2023): Chronic under-investment has led to productivity slowdown in the UK. Available at:,https://www.lse.ac.uk/News/Latest-news-from-LSE/2023/k-November-2023/Chronic-under-investment-has-led-to-productivity-slowdown-in-the-UK

[5] Centre for Entrepreneurs: Business Startup Index. Available at: https://centreforentrepreneurs.org/cfe-research/business-startup-index/

[6] Scaleup Institute (2022): The Scaleup Index 2022. Available at: https://www.scaleupinstitute.org.uk/scaleup-review-2022/annual-review-highlights/

[7] House of Lord Science and Technology Committee (2017): Life Sciences Industrial Strategy: Who's driving the bus?, Available at: https://publications.parliament.uk/pa/ld201719/ldselect/ldsctech/115/11507.htm

[8] Centre for Process Innovation, (2023) Challenges and Opportunities for UK HealthTech Manufacturing Scale-up Report. Available at: https://www.uk-cpi.com/healthtech-scale-up-report

[9] https://www.ons.gov.uk/businessindustryandtrade/changestobusiness/mergersandacquisitions/timeseries/cbau/am

5% of IPOs globally.[10] It is critical that we support our scaling firms which have passed the start-up phase to scale further by enabling their access to markets both at home and abroad.

Whilst this report is primarily focused on the regulatory experiences faced by start-ups and scaleups on their journey towards further commercial scaling, we expect that many of the report's findings will be applicable to innovative businesses at various stages of growth.

Regulation's role in the scaleup journey

Start-ups and early-stage scaling firms in the UK are facing a lot of challenges, and regulation is clearly not the only (or in many cases even the most important) contributor to their ability to scale. Other factors, such as the ability to secure talent and finance, access manufacturing facilities, or spin-out academic research play a large role in the process. In addition, it has been noted that there may be a cultural tendency and incentive for founders to sell out quickly rather than go through the process to build and scale a business.[11]

That said, regulation is an often-overlooked contributor to a start-up's success in scaling up. Regulations have the power to catalyse or block entry to market, and we have encountered examples of start-ups looking to move abroad due to prohibitive regulation. The *perceived* ease of market entry also impacts investor confidence which is of crucial value during the scaleup phase.

We strongly believe that regulation – when designed and enacted well – can be an important *enabler* for start-ups. A well-designed regulatory environment can support start-ups and scaleups to scale their businesses to the next level, for example through:

- Shaping the development of safe and effective new products and services, and supporting start-ups and scaleups to gather the necessary evidence to demonstrate such credentials;

- Providing confidence in a sector to support access to finance and investment for scaling; and

- Facilitating the creation of new and trusted markets in the UK and internationally through promoting competition, fostering public acceptance and encouraging international harmonisation of requirements.

[10] HM Treasury (2020): UK Listing Review. Available at: https://www.gov.uk/government/publications/uk-listings-review

[11] Thomas, D., Megaw , N. and Bradshaw , T. (2021) 'why have we not grown any giant companies?' the UK's attempt to take on Silicon Valley. Available at: https://www.ft.com/content/5466b46d-9cb4-479f-bf5a-1bd15783eb22.

Regulation of financing models, infrastructure development and intellectual property also play a great role in influencing the other factors mentioned above that are important to start-ups and scaleups. However, for the sake of this review, we are focusing on the regulation of the *applications of the products and servic*es that are being developed, rather than the wider ecosystem.

Project approach

This project was undertaken as a policy sprint, working to a more condensed timescale than the RHC's standard deep dive projects. To develop the conclusions reached in this report, the RHC drew on evidence from its previous reports, in addition to the following three stages of evidence gathering and policy formulation:

1. **A roundtable with venture capitalists, research institutes and start-up representative organisations.** A roundtable as part of *London Tech Week*[12] brought together stakeholders across industry and Government with expertise and experience of working with start-ups and scaling firms. The session explored the challenges that start-ups and scaling firms face when navigating regulation, and potential solutions that Government and regulators should consider. A readout from the session is included in Annex A.

2. **Interviews with start-ups, scaleups and SME founders from a range of sectors.** Using a snowball sampling approach, companies spanning six different sectors were interviewed. With the exception of those that consented to be included as case studies, no names of companies or individuals have been included in the report, to protect their anonymity.

3. **Testing of findings and conclusions with key stakeholders**. The Council engaged with teams across the policy landscape to test its findings and gather examples of existing good practice. This included a workshop with members of the cross-sector Regulators' Innovation Network.

We are very grateful to all the stakeholders who contributed their time and insights to support the development of this report.

[12] https://londontechweek.com/

Summary of recommendations

Recommendation 1: DSIT, working with the Department for Business and Trade (DBT) and relevant partners should ensure that regulators are empowered with the tools and resources to better support innovative start-ups and scaleups.

Options to implement this should be developed by policy teams and regulators, but could include:

- Establishing a flexible fund that would enable regulators to bid for additional capacity for work on technology areas with high potential return on investment for the UK, including international benchmarking.
- Reviewing mechanisms to facilitate agile legal changes to support regulatory experimentation and agile governance of rapidly developing technologies.
- Expanding government and regulator awareness of innovative regulatory science approaches such as synthetic data and digital twins. This can also include incorporating continuous evaluation and adaptation mechanisms.

Recommendation 2: DSIT should work with relevant partners to embed a greater understanding of regulation, and earlier engagement with regulatory issues, within the early-stage business community.

Options to implement this should be developed by policy teams and regulators, but could include:

- Working with relevant external bodies such as the Royal Society, to integrate regulatory training into doctoral programs.
- Strengthening regulatory involvement and support for businesses and individuals participating in existing government funded programmes, such as the Barclays Eagle Lab Growth programmes and the new Venture Capital Fellowship.
- Considering how the development of a concierge service for regulatory support can best support early-stage businesses to access regulatory support and training.

Recommendation 3: Government and regulators should continue to build the knowledge base on pro-innovation regulation, and particularly the impacts on start-ups and scaleups.

Options to implement this should be developed by policy teams and regulators, but could include:

- Encouraging regulators to evaluate the effectiveness of pro-innovation measures, such as sandboxes, on early-stage businesses, and share learnings systematically through the Regulators' Innovation Network.
- Ensuring that regulatory expertise is represented in the new Scaleup Forum, to enable it to act as a bridge to strengthen Government's understanding of regulatory impacts on the early-stage business community.
- Establishing more consistent and comprehensive monitoring of regulatory impacts on innovation, for example through an annual innovation review, which could bring together metrics on regulatory approvals, waiting times, and small business participation in regulatory experimentation initiatives.

The challenges

The pro-innovation regulation context

Before we delve into specific challenges that are faced by start-ups and scaleups, it is important to note that there are wider challenges in creating a regulatory environment that enables innovation to thrive. The Government Chief Scientific Adviser's (GCSA) *Pro-innovation Regulation Review* crosscutting paper[13] noted that regulators are facing a number of pressures and challenges in regulating emerging technologies and innovations:

Key challenges highlighted in the GCSA Pro-innovation Regulation review

"Fragmentation – technology and its many applications often cross sectoral and territorial boundaries and do not align with existing regulatory remits, leading to gaps, overlaps, duplication and inconsistency;

Pacing – technological developments often outpace the speed at which regulatory systems can respond, while introducing regulations too early can hinder the development of emergent tech;

Skills – regulators report challenges in attracting relevant skills and talent, such as digital, data and technology profession experts;

Incentives – regulators are subject to a complex set of incentives including statutory objectives and duties, with limited reward for taking risks in support of innovative products;

Capacity – pro-innovation programmes like sandboxes and innovation hubs are resource-intensive and regulators report challenges in sustaining these 'upstream' activities from existing resources."

The RHC welcomes this review and the commitment from Government in the formal response[14] to address these crucial challenges.

[13] UK Government Chief Scientific Adviser's Pro-innovation Regulation Review: crosscutting paper (2023). Available at: https://www.gov.uk/government/publications/pro-innovation-regulation-of-technologies-review-cross-cutting

[14] Dame Angela McLean's Pro-Innovation Regulation of Technologies Review: HMG's response (2023). Available at: https://assets.publishing.service.gov.uk/media/655cd137544aea0019fb31e4/_8243__Government_Response_Draft_HMG_response_to_McLean_Cross-Cutting_Base_-_November_2023_PDF.pdf

Regulatory capacity to deal with new technologies, in particular, is a challenge that the RHC has seen across many sectors, and urgently needs to be addressed. Increased resourcing for regulators is not about introducing more regulation - it is about improving the quality, speed and efficiency of regulatory delivery, helping businesses to demonstrate control of risk and of the potential for occurrence of harm (and may even equate to de-regulation). Innovators across multiple sectors have told us that resource dedicated to regulation in their sector is not proportionate to the strategic and economic importance to the UK of the technologies and innovations that they are developing.

In addition to having appropriate resourcing, a critical part of regulators' toolkit, and often one that they have limited control over, is the legal framework that they operate in. We discuss this issue in depth in Section B of the report, and suggest that Government reviews mechanisms to facilitate more agile legal changes to support anticipatory regulation.

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Specific challenges for start-ups and scaleups

In addition to the wider challenges above, we have sought to understand the specific and unique regulatory challenges faced by smaller innovators.

First and foremost, there is a crosscutting issue around the expertise and understanding of start-ups of the regulatory system. The *GCSA Pro-innovation Regulation Review* recommendations call for increasing the expertise of regulators to deal with challenges brought on by innovation, but lack of expertise is a challenge that goes both ways. We

have heard that often regulations are not understood or engaged upon during the early stages of developing a business.

We discuss options that regulators can take to support start-ups and scaleups to understand and navigate regulatory requirements below, but on a longer-term scale, it is essential to integrate regulatory discussions early in the business lifecycle. Government should promote opportunities for regulators to collaborate with academic institutions to integrate regulatory education into entrepreneurial and doctoral programmes, business advisers and tech transfer offices, with a particular focus on the five technology areas identified as part of the UK Science and Technology Framework[15].

Recommendation 2: DSIT should work with relevant partners to embed a greater understanding of regulation, and earlier engagement with regulatory issues, within the early-stage business community.

Options to implement this should be developed by policy teams and regulators, but could include:

- **Working with relevant external bodies such as the Royal Society, to integrate regulatory training into doctoral programs.**
- **Strengthening regulatory involvement and support for businesses and individuals participating in existing government funded programmes, such as the Barclays Eagle Lab Growth programmes[16] and the new Venture Capital Fellowships[17].**
- **Considering how the development of a concierge service for regulatory support can best support early-stage businesses to access regulatory support and training.**

Building capacity and capability within regulators, and embedding an understanding of regulation within entrepreneurial networks will be crucial to underpin the successful delivery of many of the policy options discussed in this report.

In addition, we have identified three specific scenarios that may be faced by start-ups and scaling firms pioneering products and services at the cutting edge of innovation, each one posing unique challenges. They are not mutually exclusive, indeed in many sectors we see

[15] DSIT: UK Science and Technology Framework (2023). Available at: https://www.gov.uk/government/publications/uk-science-and-technology-framework

[16] Further information available at: https://labs.uk.barclays/what-we-offer/our-programmes/uk-government-funded-programmes/

[17] Further information available at: https://www.gov.uk/government/news/320-million-plan-to-usher-innovation-and-deliver-mansion-house-reforms

a combination of the three scenarios, which can further complicate matters, but they are intended to frame and codify the types of challenges that start-ups are experiencing.

Scenario A: There may be uncertainty as to how new innovations will be regulated or fit under existing regulatory regimes.

Scenario B: There may be an existing regulatory regime that does not accommodate innovative new products and services.

Scenario C: There may be an existing regulatory framework that is fit for purpose, but complying with its requirements is too costly, time consuming or complex for smaller firms.

These scenarios are not unique to start-ups and scaleups, and may be experienced by businesses of all sizes, but in each case we find that smaller businesses are disproportionately challenged. This may be due to their financial pressures, their having less understanding of regulation than established companies, or the recognised institutional tendency for regulation to favour incumbent businesses.[18]

Throughout the report, we will explore the three scenarios of challenge through the stories of three innovative start-ups. We have set out a number of proposed policy options under each of the scenarios with (non-exhaustive) examples of where good practice is starting to arise. We do not expect there to be a 'one size fits all' solution across all sectors, but hope that this report sparks a continued debate around how our regulatory frameworks can be more accessible and enabling to businesses – of all sizes.

[18] D. Rodrik (2014): When ideas trump interests: Preferences, worldviews, and policy innovations Available at: https://drodrik.scholar.harvard.edu/files/dani-rodrik/files/jep2e282e12e189.pdf.

Scenario A: there may be uncertainty as to how new innovations will be regulated or fit within existing regulations

For entirely novel products and services, there may be uncertainty as to how the innovation will fit under existing sectoral regulation and how compliance can be achieved - there may in some cases not even be any existing regulatory regime in place. This is more likely to be the case for 'disruptive' innovations, those that step outside of existing paradigms, which may involve new areas of R&D, new modes of production or routes to market. Start-ups and scaling firms, by their disruptive nature, and with their generally higher appetite for risk, frequently develop new technologies and products that fit into this category.

In some sectors, this lack of regulation has led to rapid innovation at the expense of consumer protection (this has been widely discussed in the case of developments in 'Big Tech').

However, less often discussed is the innovation-stagnating effect that a lack of regulatory certainty can pose. In sectors where some form of regulatory authorisation or standardisation of rules is required to market a product, uncertainty around the regulatory processes can completely impede public access to potentially beneficial innovations. This can be detrimental to start-ups and scaling firms who depend on the support and confidence of investors that there is a clear pathway to market for their products.

The solution is not as simple as rushing to put new regulations in place that provide protection and certainty, as there can be a risk of moving too early and locking in regulations that are not proportionate to the risks posed by the innovation, once such risks are better understood. Instead, there are a number of actions we outline below that regulators, policymakers and innovators can take to assess the risks, co-create new regulatory regimes, and signal the regulatory direction of travel to provide confidence to investors. We also refer to the advantages of facilitating development of private mechanisms, especially standards and accreditation, along a pathway towards more formal regulation, if necessary.

Case Study: Apian

“At Apian, we are using drones to transform healthcare logistics by bringing everyday on-demand delivery to the NHS, resulting in faster deliveries to more patients for less emissions.

Apian's technology platform integrates the healthcare industry with the drone industry to create a fully autonomous delivery system operating at national scale. Our Health and Logistics API is a multi-sided marketplace that connects healthcare systems with drone operators. It takes healthcare orders, selects a carrier, optimises the schedule and routing, and provides real-time tracking of the payload location and its integrity.

Apian collaborates with both aviation and healthcare regulators. While many in the industry express frustration with the Civil Aviation Authority (CAA), we commend the regulator for prioritising healthcare applications. However, the Department for Transport (DfT) must set a target date for the implementation of its vision for non-segregated airspace. This presents **challenges for commercialisation and our investors who lack clarity regarding the time frame for sustainable operations and revenue generation**. A declaration akin to JFK's 1962 statement, 'to land a man on the moon by the end of the decade,' is essential, along with increased funding for the regulators.

The application of drones in the healthcare sector whilst innovative is one that has been held up by regulatory uncertainty. **The Medicines and Healthcare products Regulatory Agency (MHRA) lacks a regulatory framework for the delivery of medical products via drones.** Each healthcare provider must conduct validation tests prior to obtaining authorisations. The MHRA and CAA have not established a

standardised framework for healthcare providers to validate these drone-delivered products.

In addition to regulatory uncertainty, Apian has also faced challenges with current regulations including time-consuming Unmanned Aircraft System operator authorisation procedures, and restricted trials of between 3 to 6 months which are not conducive to further testing and improvement.

The impact of this is that regulatory delays have a cascading effect that ultimately hinders the benefits for the healthcare sector (e.g., initial analysis indicates annual savings of £400 million for the NHS).”

Collaboration opportunities can help start-ups and scaleups to work with regulators and industry to co-create new regulations

a. Collaboration between regulators, start-ups and scaleups through regulatory experimentation

As our *Closing the Gap* report highlighted, regulatory experimentation initiatives such as sandboxes, test beds and digital simulation (outlined below) provide opportunities for start-ups, scaleups and regulators to test out regulations for new products and services within a controlled environment. They have the explicit aim of learning about what happens subsequently to inform the development of future regulatory approaches.

When implemented well, experimental regulatory approaches provide an important mechanism to gather insight into the safety and effectiveness of new innovations and involve start-ups in the development of new regulations. In addition, such approaches can be useful to examine how new innovations may fit into existing regulatory schemes as well as helping to increase small businesses' general understanding of the regulatory environments that do or will apply to their sector.

There needs to be a co-ordinated approach to solving common problems across sectors/ regions and learning from parallel regulatory approaches elsewhere (in different sectors and/or different countries). Encouraging innovators and regulators to explore adjacent – or even very different – sectors through experimentation could help develop and adapt technologies and (in parallel) regulatory regimes, and shorten time to market – for example by developing a range of potential market use-cases for technology developers and regulators to understand.

Types of regulatory experimentation

Sandboxes

Sandboxes are experimental approaches which offer supervised real-life or simulated test environments where innovators can trail new products, services or business models, often under relaxed regulatory requirements. They are designed and delivered independently by regulators and are not a tool for deregulation. These are particularly powerful when linked to data access.

Testbeds

Testbeds have a broader scope than regulatory sandboxes, often operating in environments with a significant industrial component, and do not always seek to create an appropriate regulatory environment, and may be developed primarily to test proof of concept. Regulators' involvement in a particular testbed can be useful to identify future regulatory implications, and is usually agreed between the regulator and the consortium driving the testbed forward, such as a local authority.

Digital simulation

Where products are in early-stage development and there are safety concerns surrounding testing their deployment even in controlled settings, digital approaches such as digital simulation or twins can be useful. Digital models can be used to generate a virtual copy of a system in which interventions could be trialled. For example, virtual traffic models have been generated to test the interactions of autonomous vehicles, and the computational modelling has been used to better understand drug interactions.[19] [20]

Throughout the RHC's work, we have identified several examples of regulatory experimentation and note a number of considerations that are important to ensure that they best support smaller innovators:

- **Regulators should be empowered to introduce more sandbox-type early collaboration investigative mechanisms, ideally incorporating access to 'open data'.** Sandbox-type mechanisms are now widely being introduced, and this should be encouraged across all regulatory systems. In addition, consideration should be given to embedding regulatory considerations in alternative experimental approaches such as testbeds and digital twins or simulation, as outlined above. When designing such initiatives, regulators should ensure that the entry criteria are suitably accessible to low technological readiness level (TRL) innovative businesses;

- **Regulators should ensure that insights arising from experimental regulatory initiatives are fed back to inform the continuous learning and improvement of**

[19] Catapult Transport Systems (2018): regulating and accelerating development of highly automated and autonomous vehicles through simulation and modelling. Available at: https://cp.catapult.org.uk/wp-content/uploads/2021/07/00299_AV-Simulation-Testing-Report.pdf

[20] Frangi, A. et al. (2023): Unlocking the power of computational modelling and simulation across the product lifecycle in life sciences: A UK Landscape Report. InSilicoUK Pro-Innovation Regulations Network. Available at: doi: 10.5281/zenodo.8325274

regulatory processes. Innovators have noted that in some cases, 'sandbox' initiatives are acting more as an entry point to engagement with the regulator, but not leading to any change in the regulatory framework to support innovative new businesses, either due regulators' inability to amend the rules or a lack of cultural buy-in within the regulator. In some cases, where new innovations are being tested against an existing regulatory framework, it may not always be necessary to make changes to the regulatory framework, but it is still important that there is an element of learning, by both the regulator and the innovator;

- **Regulators should consider how to best communicate and raise awareness of sandboxes and other experimental initiatives with start-ups, scaling firms and business advisors.** We heard inconsistent perceptions of how sandboxes work, and some start-ups we spoke with were concerned about reputational risk of undertaking this route versus the standard authorisation pathway in their sector. Even more worryingly, in a recent survey of AI start-ups, Startup Coalition (formerly Coadec) found that 35% of those surveyed were not aware of the existence of sandbox initiatives at all;[21] and

- **There need to be adequate mechanisms for innovators to leave the sandbox and not be impeded in scaling their products**. The challenge of 'exiting' the regulatory sandbox is one that has been widely acknowledged, but is particularly important for smaller firms at a crucial phase of seeking to scale their operations. 'Scaleboxes' have been proposed as a solution to this, but further work is needed to understand how they may work in practice.[22]

Information Commissioner's Office (ICO) Sandbox[23]

The ICO has developed a regulatory sandbox service to support organisations who are creating products and services which utilise personal data in innovative and safe ways. The service has so far supported a number of smaller firms and start-ups since its inception in 2020.

[21] Coadec (2022): What do AI Startups Want from Regulation?. Available at: https://coadec.com/wp-content/uploads/2022/07/05072022-AI-Report-For-Publication.pdf

[22] HM Treasury (2021): The Kalifa Review of UK FinTech. Available at: https://www.gov.uk/government/publications/the-kalifa-review-of-uk-fintech

[23] ICO: Regulatory Sandbox. Further information available at: https://ico.org.uk/for-organisations/advice-and-services/regulatory-sandbox/

In addition to supporting innovators and organisations to better understand the regulatory process, the ICO is proactively using the sandbox to gather insights to develop future regulatory approaches to new technologies. It has selected 'emerging technologies' as one of its current priority areas of focus for the regulatory sandbox, with the aim to use the lessons learned in the Sandbox to develop their views and guidance.

b. Collaboration between start-ups, scaleups and other industry players through standards development

Regulators are not the only players in setting the requirements and norms for new technologies. Increasingly, regulatory requirements are emerging from sources other than the regulator, such as the development of industry-led standards and norms. In some cases, the rise of industry-led norms can create challenging additional requirements for start-ups and scaling firms, but it is worth noting the important role they can play in providing frameworks for industry to follow in the absence of, or to supplement, statutory regulation. Research commissioned by the former Department for Business, Energy and Industrial Strategy (BEIS) highlighted the role that standards can play in providing minimum levels of quality for emerging technologies to avoid accidents that may undermine trust in new products.[24]

Standardisation, as a collaborative industry-led process, also provides natural opportunities to share information and tools. They can provide an important forum for information exchange and partnership across industry, which may include start-up partnerships with established incumbents.

Therefore, it is important that start-ups and scaleups are aware of, and have access to, opportunities to co-develop standards with industry colleagues for technologies that they are working on.

Unfortunately, it has been noted that this is not always the case. Research has found that in the field of AI, for example, standardisation efforts are dominated by larger organisations with the time, resource and funding to dedicate to such activities.[25] The process of

[24] DBT, BEIS (2022): Role of standardisation in support of emerging technologies. Available at: https://www.gov.uk/government/publications/role-of-standardisation-in-support-of-emerging-technologies

[25] DCMS, OAI (2022): Understanding UK AI R&D commercialisation and the role of standards. Available at: https://www.gov.uk/government/publications/understanding-uk-ai-rd-commercialisation-and-the-role-of-standards

accessing and sponsoring standards documents, in itself, is costly, with each Publicly Available Specification (PAS) standard costing around £80,000-£100,000 to develop.[26]

Government can play an important role here in creating spaces that foster more equitable participation in standards-development efforts. The Joint Action Plan for Standards for the 4th Industrial Revolution is beginning to address this[27], in addition to promising initiatives that are arising such as the AI Global Standards Hub (outlined below) and Innovate UK and British Standards Institution's (BSI) work to make standards accessible for innovators to view for free via the EDGE portal.[28]

AI Standards Hub

The AI Hub is a UK Government supported initiative led by The Alan Turing Institute in partnership with the British Standards Institution (BSI) and the National Physical Laboratory (NPL).

The Hub recognises the complexity of the international standards landscape, particularly for underrepresented groups such as start-ups. It aims to 'help stakeholders across industry, government and regulators, civil society, and academia understand, use, and develop standards' through providing resources such as databases for standards, policy and research, online training materials and community forums.

The development of the Hub was guided by a series of workshops, including with start-ups and scaleups, to understand user needs.[29]

Clear communication of political direction and vision can increase investor confidence in the absence of a clear pathway to market

For nascent technologies where the development of an appropriate regulatory position is likely to take significant time, long term vision statements or policy 'steers' can help to bridge the gap and provide industry and investors with the necessary confidence to scale their products in the UK. Stakeholders have told us that statements confirming consistent

[26] (see 24)

[27] UK Government Action Plan on Standards for the fourth Industrial Revolution (2021). Available here: https://www.gov.uk/government/publications/standards-for-the-fourth-industrial-revolution-action-plan

[28] Innovate UK EDGE service. Further information available here: https://www.bsigroup.com/globalassets/localfiles/en-gb/knowledge-services/bsi-helping-smes-to-scale-and-grow.pdf

[29] AI Standards Hub. Further information available at: https://aistandardshub.org/

policy directions and political affirmations around emerging technologies can have a significant impact in increasing investor confidence, ensuring startups and scaling firms have the necessary funding to scale further. Clear statements of intent are also important in cementing the UK's international leadership on technology governance, as has been exemplified by global recognition of the UK's proportionate approach to regulating AI.

Government should also create 'innovation diffusion and adoption roadmaps' for key sectors where the UK has a strategic global advantage, setting out how they will be supported in diffusing innovations to ensure widespread adoption.

Additionally, whilst political changes in direction may be unavoidable, Government and regulators should ensure that the direction is at least communicated rapidly and transparently. This is particularly important in the context of continued political uncertainty generated by the UK's departure from the European Union. For example, we have heard from SME's operating in the medtech sector that cite uncertainty around the UK's approach to regulating medical devices in a competitive global marketplace as the greatest challenge that they are facing in expanding and continuing their operations, and note that this is a widespread industry concern.[30]

'Towards Fusion Energy' – The UK Government's fusion strategy

Despite fusion energy being far from commercialisation, the UK has grown a strong ecosystem of companies of different sizes, including start-ups, developing promising technologies to support fusion energy.

One contributor to this success has been the Government's public commitment to being a UK leader in this space, and intentions to develop a 'proportionate regulatory framework' as set out in its fusion strategy in response to a consultation.[31]

Since the RHC's *Report on Fusion Regulation*[32] was published in 2021, we have heard from stakeholders that the UK's clearly signalled proportionate approach to regulating this technology was a key factor in their decision to invest in the UK fusion market.

[30] The state of EU Medical Device Regulation (MDR) readiness in UK SMEs (https://www.ukri.org/wp-content/uploads/2021/12/IUK-171221-UK-SME-MDR-ReadinessFinalReport.pdf

[31] DESNZ, BEIS (2023). Towards fusion energy 2023: the next stage of the UK's fusion energy strategy. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1022540/towards-fusion-energy-uk-government-fusion-strategy.pdf

[32] RHC (2021): Regulatory Horizons Council: report on fusion energy regulation. Available at: https://www.gov.uk/government/publications/regulatory-horizons-council-report-on-fusion-energy-regulation

Regulators can play an active role in creating new and trusted markets through driving the development of safety norms and facilitating data access

a. Proactively developing the understanding of the risks associated with emerging technologies and regulatory approaches to mitigate them

The UK needs to strike a balance between safety/security and growth/rapid innovation, where there are often conflicting interests. Having a strong rule of law and high level of assurance is an asset for the UK, where our regulatory regimes are trusted and considered to act as 'due diligence' giving start-ups a passport to exports.[33] Regulation is not 'one size fits all' and often the UK is not operating unilaterally but needs to consider and align with wider international regulatory systems, requiring a co-ordinated holistic approach – including consideration of the ethics and potential for disproportionate impact on particular groups or disadvantaged people. We need to regulate applications not the technologies themselves, building on case studies, learning from other countries' regulatory regimes and 'backcasting' from potential future scenarios. We need to get better at anticipating and preventing unforeseen consequences – in some instances where there are risks to the planet, or to human life, anticipatory 'future-proof' regulation needs to be put in place to prevent risk arising; while in other instances regulation needs to respond quickly as threats emerge.

When developing new regulatory approaches for emerging technologies that take due account of all of these points, the basic questions that have to be answered are:

- What is the system for identifying the risks and harms that occur with this product, service or market? Who will identify the relevant information, and how is it to be shared with others? Who needs to evaluate the data, and implement actions to manage it?
- How will risks and harms be evaluated as acceptable (or not), and balanced with realistic potential benefits, and who needs to be involved? This typically involves technical expert evaluation, but it may also need the involvement of wider society if ethical considerations are involved.
- How will risks be managed, so as to deliver successful and acceptable outcomes? What actions might need to be taken by whom?

[33] WJP rule of law index (2023) World Justice Project. Available at: https://worldjusticeproject.org/rule-of-law-index/country/2023/United%20Kingdom/Regulatory%20Enforcement/

All regulatory systems need to answer these questions. The questions need to be answered holistically in order to deliver an effective *system*, and will usually require the involvement of multiple actions from public, private and civil society. (This is a different viewpoint from looking at regulation just as what requirements regulators impose on regulatees – in reality, all have functions to perform if the system is to operate well.)

The components of an effective regulatory system can be constructed throughout the period of research and development, creating a series of individual building blocks. For example, tests on a compound or prototype will produce data on the safety and effectiveness of the compound or prototype. The nature of this information should indicate what tests or controls might be relevant in order to manage the risks that arise. Thus, the building blocks of standards, tests, conformity assessment and so on can be crystalised over time. In this way, *an evolving pathway* around safe and effective use, risk and harm, and their evaluation and control, can identify the essential elements of what will become a regulatory system. Such a system can also emerge as stages of private and public elements, and regulators should consider opportunities to partner with academic institutions and innovative start-ups and scaleups when building this evidence.

Regulators also need to tap into regional and local networks, third sector, community groups to explore how innovations may play out differently for different groups, enabling better regulation as well as fulfilling their obligations under the Public Sector Equality Duty. Having a better on-the-ground sense of impacts is important, in order to spot challenges and engage people in adopting innovations.

Developing a robust understanding of the risks of new technologies, how these can be identified and mitigated will help regulators take a proactive role in fostering new markets for disruptive technologies and can help avoid the introduction of regulation for new technologies that is too early.

Singapore's Future Ready Food Safety Hub 'FRESH'

The FRESH Hub was established by Nanyang Technological University (NTU), Singapore Food Agency (SFA) and the Agency for Science, Technology and Research (A*STAR), with the aim to drive food safety science and innovation in Singapore.[34]

It seeks to close the gap in scientific research in food safety risk assessment to support novel product development, provide a "neutral platform" for stakeholders across the food R&D ecosystem to collaborate, and accelerate the time to market for novel products by addressing food safety issues early on in the process.

[34] Nanyang Technological University: FRESH: Future Ready Food Safety Hub. Further information available at: https://www.ntu.edu.sg/fresh

The Hub also offers a consultancy service for innovators to guide them through the regulatory process and review safety data to assess their level of readiness for regulatory submission.

Singapore's regulatory partnerships with academia have played a key role in opening up the domestic market for alternative proteins, with the first cultivated meat company receiving market authorisation for commercial sale in 2022.[35]

b. Catalysing innovation through data

There are many ways in which regulators can use data to catalyse innovation. Access to high quality data is a key enabler to developing innovative new products and services. Open access to data can promote competition by providing businesses, including start-ups and scaling firms, with valuable market insights, reducing barriers to entry, inspiring innovation, and enabling data-driven decision-making.

Many firms depend on high quality data to develop their products, for example, technologies such as AI and machine learning models, are particularly reliant on access to high-quality training data to validate their effectiveness and safety (including equity considerations). We heard calls for a greater role of the regulator in facilitating and sharing data with start-ups that may support their product development. The regulator, working in collaboration with Government, can play a vital enabling role in providing access to datasets that are regulated to ensure quality (including identification of potential biases) and privacy protection. Such access to regulated data sets can enable developers to train or test their models against a benchmarked data set.

In some cases, data may be owned or need to be collected from multiple actors. Thought should be given to the system for collecting and managing all the relevant data, and defining who should contribute what data and who may access what data.

Different actors (such as researchers, entrepreneurs, funders) may have individual rights in some data, and may wish to allow certain others to access some part of that data (perhaps in anonymised, aggregated form). An effective system for doing this can be to license an independent trusted data controller for a technology or a sector, who holds the complete data set as it grows, and may be authorised by owners or contributors to allow specific access to certain categories of data.

Existing examples of this model operate in many consumer markets. Data on consumer complaints and inquiries are held by a single consumer Ombudsman (present in many

[35] BBC (2020): Singapore approves lab-grown 'chicken' meat. Available at: https://www.bbc.co.uk/news/business-55155741

sectors such as in financial services, energy, communications). The Ombudsmen, acting as sectoral data controllers, identify trends and issues from the aggregated data, and feed these back to providers, consumers and regulators, appropriately anonymised.

Consideration should also be given to the role of synthetic data – artificial data that closely mimics the properties and relationships of real data. This approach can be helpful in overcoming gaps in data representation and mitigating privacy concerns but requires careful supervision to ensure its resemblance to real world data, and questions remain as to whether this form of data should still be classified as 'personal data'.[36]

Synthetic datasets to support the development of medical technologies tackling COVID-19

The MHRA, funded by the *Regulators' Pioneer Fund* (RPF), undertook a research programme to understand the utility of synthetic datasets for testing and validation of technologies used to assess COVID-19 disease. The datasets mirror typical symptoms, diagnoses and treatments based on anonymised primary care data.

The datasets have been made available to innovators looking to test their AI-based medical devices or algorithms for accuracy and reliability and in trials were found to make the validation process much quicker for innovators to bring high quality products to patients.[37]

The datasets were produced by a collaboration between the Clinical Practice Research Datalink (CPRD), MHRA Medical Devices Division and researchers at Brunel University.

MHRA continue to undertake work in this area. With further funding from the RPF, they are looking at using high-fidelity synthetic data to create artificial control groups for clinical trials, increasing patient access to potentially beneficial treatments.[38]

[36] Colin Mitchell and Elizabeth Redrup Hill (2023) Are Synthetic Health Data 'personal data'?, PHG Foundation. Available at: https://www.phgfoundation.org/report/are-synthetic-health-data-personal-data

[37] Kantar (2021): Evaluation of the Regulators' Pioneer Fund (Round 1) – Project Descriptions. Available at: https://assets.publishing.service.gov.uk/media/604230e08fa8f577c808942d/evaluation-of-rpf-project-descriptions.pdf

[38] MHRA to receive nearly £1m beis funding to unlock digital, data and Scientific Regulatory Innovation (2022) GOV.UK. Available at: https://www.gov.uk/government/news/mhra-to-receive-nearly-1m-beis-funding-to-unlock-digital-data-and-scientific-regulatory-innovation

Scenario B: there may be an existing regulatory regime that does not accommodate innovative new products and services

For the large majority of start-ups and scaling firms, there is an existing set of regulatory requirements in place in the market they are operating in. Where such regulations are not up to pace with the speed of technological developments, start-ups and scaling firms may come up against requirements which are irrelevant, duplicative, or disproportionate to the risk of their innovation.

There are various factors that can contribute to this misalignment: regulators may have less expertise in innovative new technologies and services, may engage more widely with established industry players with longstanding connections to the regulator, or regulatory and standards development may be driven by actors with more resources and capacity. The latter issue has been said to lead to an 'incumbency bias', and tendency for regulatory regimes to favour more established industry players who may engage in rent-seeking behaviour (such as pushing for stringent regulations that hinder competitor firms).[39]

This scenario highlights the importance of mechanisms for early identification and resolution of areas where existing regulations pose a challenge for new products and services. We outline a number of options that regulators and policymakers can take to implement this.

[39] Fingleton, J. (2023) Economic Regulation and productivity, Fingleton. Available at: https://fingleton.com/insights/economic-regulation-and-productivity/

Case Study: Hoxton Farms

"At **Hoxton Farms**, we grow real animal fat – without the animals. Cultivated fat is the missing ingredient that makes irresistible meat alternatives which look, cook and taste like the real thing. We start with stem cells from pigs, which would have developed naturally into fat inside the animal, and grow the cells into juicy, delicious fat in cultivators in a process similar to brewing beer. We will sell our cultivated pork fat as an ingredient to combine with plant-based protein to enable delicious, sustainable products for consumers.

After Brexit, the UK retained EU law and inherited regulatory processes to govern novel foods which were not developed with innovation in mind.

Any food that was not eaten regularly by consumers in the UK or EU prior to 1997 is considered a novel food. Our fat is identical to pork fat that you would see in traditional meat, on the side of pork belly or bacon. However, we are growing our cultivated fat using a new process and it therefore requires novel foods authorisation before it can be placed on the market in the UK. **We'd ideally like to see a specific pathway for cultivated meat, that is tailored to these products**, similar to the processes developed by the US and Singapore.

Innovative processes for food production require a collaborative approach to regulation. The current approach is not collaborative: regulators wait for a full dossier with details of all of the processes developed in full before they will discuss any details of the new technology. This approach is the norm for many regulatory agencies and is detrimental to the innovation the UK is trying to foment across industries, **as companies have to make significant time and capital investments with limited regulatory information**

to inform their process development. Two other interrelated challenges are funding and approval timelines. Many regulators, like the Food Standards Agency (FSA), are underfunded and overstretched, leading to longer decision timelines that delay time to market.

We have an opportunity now to adapt regulations, such as the novel foods process, to enable the UK to become a world leader in tech, including food tech. For example, in our realm, the FSA has made great strides, including recently publishing guidance on cell-cultivated products. The FSA has also demonstrated openness to engage with cell-cultivated companies to develop legislation that protects consumers' safety while encouraging innovation. We are excited to see more emphasis from policymakers on progressing regulation of transformative technologies like cell-cultivated meat."

Start-ups and scaleups need regular opportunities to flag concerns with existing regulatory regimes

The simplest way to ensure that regulators are aware of issues with their regulatory requirements is through open dialogue between regulators, start-ups and scaleups. This can be achieved through engagement events and forums where innovators can interact directly with regulators to voice their concerns, in the form of open drop-in sessions, or more formal workshops.

Whilst not a substitute for direct engagement with companies, partnering with startup incubators and accelerators can also be a helpful mechanism for regulators and Government to disseminate regulatory information and gather feedback. These institutions are at the forefront of supporting startup and scaleup growth and can serve as valuable intermediaries. Regulators should make use of initiatives such as the Catapult Network[40] and Innovate UK's EDGE[41] support service for innovators to strengthen links with the start-up community and create opportunities for two-way exchange of feedback. The RHC also has an open portal for innovators to flag challenges that they are facing with regulations.[42]

Greater regulator engagement with innovative start-ups and scaleups can also help regulators to build their understanding and expertise in cutting-edge technology areas, a challenge that we discuss next.

Start-up and scaleup expertise should be represented in regulators' organisational structures and Boards

Many innovators voiced frustration that regulators do not understand their business models sufficiently to advise on regulation. The rapid pace of technological innovation creates inevitable challenges for regulators to keep up, and this may be particularly pronounced for innovative start-ups and scaleups operating at the cutting edge of their field. This challenge is prevalent across the innovation ecosystem more generally, and was discussed in the GCSA *Review of Pro-innovation Regulation*, but is compounded for start-ups by a perception that regulators do not understand the unique challenges and business models that they operate in. A recent investor survey by Startup Coalition found

[40] For more information, see: https://catapult.org.uk/

[41] For more information, see: https://www.innovateukedge.ukri.org/

[42] RHC Commissioning Form. Available at: https://forms.office.com/pages/responsepage.aspx?id=BXCsy8EC60O0I-ZJLRst2CT-u_kWn1pKkmgeaxr6OnpUOVNQSTZDUFM4UkNGR0ZDUTNURFg1SDhFSi4u

that 60% of investors surveyed felt that regulators had only a “basic understanding” of tech startups, a further 22% thought regulators had none at all.[43]

Regulators ensuring that their organisational design and advisory structures have expertise in a) the challenges faced by start-ups and scaling firms and b) cutting edge sectoral innovation can help to ensure that decision making is not inadvertently biased towards incumbent business models.

Cross-regulator collaboration can help to identify and address areas of duplication or friction caused by technology convergence

Working in sectors overseen by a number of different regulators can lead to sometimes disproportionate regulatory requirements to comply with, as well as contributing to the complexity burden for small businesses.

Where there is insufficient join-up and alignment on regulatory asks, duplicated asks from multiple regulators can lead to avoidable burdens on businesses. For example, we heard of challenges of start-ups and scaleups operating across the utilities sector that are dealing with similar requests for information from each of the utilities regulators which could have been avoided if there were mechanisms in place to share data between regulators or align requests. This problem is not unique to start-ups and scaleups, but like many of the issues we discuss, can be pronounced for these smaller businesses that are developing disruptive innovations. It is also an issue that we can only expect to increase, as a common feature and challenge of emerging technologies for both developers and regulators is the convergence issue – that new innovations blur traditional sectoral boundaries.

Mechanisms for regulators and Government departments to collaborate, share learnings and align their ways of working will be increasingly important. It is important that such mechanisms go beyond being a ‘talking shop’ and lead to genuine collaboration in how they undertake their regulatory activities. Here are some examples of how this should work in practice:

- Horizon Scanning and exchange of information around shared areas of interest;
- Alignment of regulatory requirements to ensure a clear and proportionate regulatory pathway to market for technologies that span multiple regulators; and

[43] Coadec, The Entrepreneurs Network (2022): Tech Startup Manifesto 2022. Available at: https://coadec.com/wp-content/uploads/2022/07/2022-Startup-Manifesto-Final.pdf

- Data sharing and mutual recognition of shared regulatory requirements (which could take the form of a 'regulatory passport') to avoid duplication of asks.

Promisingly, there are a number of sector specific cross-regulator collaborations that are beginning to emerge, such as the Digital Regulation Cooperation Forum (outlined below) and the Engineering Biology Regulators' Network. It will be important that these networks establish a strong presence amongst the start-up and scaleup community.

The Digital Regulation Cooperation Forum (DRCF)

The DRCF is a collaboration between the Competition and Markets Authority (CMA), Information Commissioner's Office (ICO), Ofcom and the Financial Conduct Authority (FCA), established to promote greater regulatory co-operation and coherence in digital regulation.

Amongst other priorities, the DRCF's 2023/24 workplan includes a workstream on promoting 'collaboration' between the four agencies, including a join project on the governance of algorithmic systems and the development of a new cross-regulator innovator support service pilot.

The workplan recognises the importance of wide stakeholder engagement on its projects, including with the start-up community.[44]

The UK's regulatory system requires greater ability to suspend or amend existing rules

The logical response to an unnecessary collision between an existing rule and a new situation is to adapt or remove the rule, or create a tailored exemption from it. The challenges here are that, firstly, this needs to be done quickly if it is to facilitate useful innovation and, secondly, it is traditionally a task for Parliament and Government, rather than for regulators. Legislative freedoms to amend or suspend rules are also an important requirement for delivering some regulatory sandbox or experimentation initiatives, as discussed above. However, this is an important gap in the regulatory toolbox that should be available for all regulators, to facilitate pro-innovation culture and effective, speedy delivery. Such a mechanism would need to take account of and balance relevant

[44] Digital Regulation Cooperation Forum. Further information available at: https://www.drcf.org.uk/home

considerations of protection, risk, benefits, innovation, growth and other aspects. But we recommend that changes can be made that observe considerations of constitutional governance, maintaining adequate protection, and delivering speedy support for innovation. Such a change would be a game changer, and no country has done it.

The power to agree derogations or permit flexibility might operate differently in different contexts and sectors. It might, for example, be inherent within a regulatory structure, permitting operators flexibility in how they comply with essential outcome requirements through ‘acceptable means of compliance’ (a phrase used in aviation safety regulation), but many regulatory systems do not have such flexibility. In other contexts, there might be a power for a regulator to exercise discretion in permitting specific arrangements within a sandbox scheme, or to derogate or disapply existing rules in certain circumstances. Powers might be exercised subject to advice or approval by a suitable committee of experts and stakeholders. Alternatively, an independent committee might be empowered to make the decision, perhaps even a single centralised committee so as to avoid unnecessary bureaucracy. Further, a Minister might have such as power, perhaps subject to notification and a ‘negative resolution’ procedure by Parliament.

Thus, a number of options might be relevant, some more swift and flexible than others. We recommend that all major sectors where innovation is relevant should review (involving business and other stakeholders, as well as regulators) what approach would be appropriate in their context so as to facilitate innovation. The review should invite views on the circumstances and conditions that should apply to the experiment, and what protections, how to decide what level of risk is acceptable, and what arrangements should exist for redress if harm occurs.

Scenario C: the existing regulatory framework may be fit for purpose, but complying with its requirements is too costly, time consuming or complex for start-ups and scaleups.

It is not always the case that new innovation requires a change to the regulatory requirements, and it may be the case that existing regulation can be adequately applied to the new product or service. For example, stakeholders we engaged with on the RHC's review of the regulation of AI as a Medical Device largely cautioned against AI exceptionalism, and emphasised the need to first consider how existing software as a medical device regulation may still apply.[45]

However, in this case we are seeing a third scenario of challenge for start-ups and scaling firms that pertains to the *implementation* of the regulations or requirements, and associated *cultures* in delivery. This could be that the cost or time required to undertake regulatory approval/authorisation is prohibitively high, or it may be more subtly that the regulations are (or are perceived to be) so complex that new entrants are dissuaded from entering a sector, rather than helped. It is worth noting that this issue can be exacerbated when there are multiple regulatory regimes governing a particular innovation.

Therefore, in general, the more complex the regulatory environment, the more likely the field is to be dominated by larger incumbents with the resources to manage the complexity.

In this section, we outline options that should be considered when implementing existing fit-for-purpose regulatory approaches to ensure that they are more accessible to companies of all sizes.

[45] RHC (2022): Regulatory Horizons Council: The regulation of Artificial Intelligence as a Medical Device. Available at: https://www.gov.uk/government/publications/regulatory-horizons-council-the-regulation-of-artificial-intelligence-as-a-medical-device

Case Study: JET Connectivity

"At JET Connectivity, our focus is on developing high-speed, reliable sea connectivity to enhance safety, safeguard the environment, and promote stable growth in the global blue economy and digital ocean. Our innovative semi-submersible 5G platform, housed on floating buoy platforms, is designed to provide resilient 5G connectivity, offering real-time data acquisition and transmission for maritime operators. This system allows users to connect seamlessly from their devices, operating offshore as effortlessly as on land, without the infrastructure or costs associated with fibre or satellite communications.

Securing a Maritime Management Organisation (MMO) license to deploy our 33 ton, 22 meter tall semi-submersible 5G platform required engagement with various national and regional regulatory authorities, including the Maritime and Coastguard Agency (MCA), Natural England, Historic England, and the local authority. **The process took twice as long as initially estimated, totalling 24 weeks and resulting in significant overspending.**

Whilst individual regulatory engagements were prompt and helpful, **challenges arose due to the lack of coordination among regulatory bodies and unforeseen additional requirements that were not initially communicated.** These delays not only impacted our operations but also had a cascading effect on other stakeholders within the consortium, which was partially grant-funded by the Offshore Renewable Energy Catapult.

Despite operating within an offshore wind farm unlikely to be frequented by fishing or recreational boats, regulatory requirements did not consider this reduced risk. This led to the necessity for full archaeological assessments and engagement with local fisheries and recreational organisations.

Moreover, when exploring the deployment of our 5G masts in other regions, we encountered differing requirements that could benefit from greater alignment at the national level."

Clear communication and streamlining of regulatory information and guidance can reduce the complexity burden for start-ups and scaleups

For many start-ups and scaling firms, who may be new to regulated industries, knowing what regulatory frameworks and requirements exist, and how to navigate them, can be a great challenge. Start-ups and scaleups we engaged with spoke of challenges interpreting often complex and technical regulatory documents, knowing who to speak to within the regulator, and managing regulatory requirements that are spread across regulators. For this reason, many smaller firms rely on outsourcing costly consultant support, but not all companies will be in a financial position to do so.

People and businesses often communicate within the frameworks that are familiar to them. But the successful exploitation of innovations often challenges existing siloed conversations. Hence, there is a need to enable overviews and to connect people in new ways. This is particularly needed where, as is often the case, new products, services and markets encounter multiple regimes/regulators.

Where possible, innovative methods to rapidly disseminate information should be considered, utilising relevant intermediaries, regional networks and trade associations. Some start-ups and scaleups we engaged with emphasised that information published on Gov.uk is not always easy to find and accessible. Some regulators and Government Departments have set up industry newsletters, such as the 'DSIT Download'[46], which can help to close the communication divide.

NHS AI and Digital Regulations Service for health and social care

The AI and Digital Regulations Service is a collaboration between the Medicines and Healthcare products Agency (MHRA), the Care Quality Commission (CQC), the Health Research Authority (HRA) and the National Institute for Health and Care Excellence (NICE). It provides streamlined regulatory guidance from across the four agencies for developers and adopters of AI and Digital technologies. The service supports innovators to prioritise their efforts, for example through indicating where guidance is 'required' vs 'best practice'.[47]

[46] DSIT Download: https://www.linkedin.com/newsletters/dsit-download-7096775982023356417/

[47] NHS: Understanding regulations of AI and digital technology in health and social care. Available at: https://www.digitalregulations.innovation.nhs.uk/

Partnering with established firms can help earlier stage businesses to navigate regulatory landscapes

In this section so far, we have emphasised the role of Government and regulators in making the regulatory landscape more accessible to start-ups and scaleups. Whilst that is vital, we shoudn't overlook the value of industry knowledge sharing and partnerships. This could take several forms, for example we previously discussed the role of standardisation in facilitating this knowledge sharing, but it is also something that the regulator can facilitate.

Regulators have the advantage of being linked in with industry firms who have successfully navigated regulations. In some sectors and scenarios, mentoring or partnership schemes, convened by Government or the regulator, are an innovative way to foster greater industry collaboration. Ofwat has already run such a scheme with success, which we describe below.

Ofwat Water Discovery Challenge: Sector Mentoring

As part of the Water Discovery Challenge, Ofwat offers finalists and winners up to £500k financial support together with a sector-led mentoring programme, with the allocation of a mentor from a regional water or wastewater company in England and Wales.

Mentors work directly with early-stage innovators, providing bespoke support and guidance, insights into the water sector, and form a useful mechanism to support new entrants to navigate regulatory processes. Mentors also support through signposting to other stakeholders in the sector and useful resources. [48]

Expedited or iterative approaches to regulatory approvals should be considered to reduce waiting times

We heard of several cases, across sectors, where authorisation waiting times of 12-18 months are causing challenges for start-ups and scaling firms that are under pressure to receive financial returns. Such waiting times may also put off potential new entrants from operating in what are perceived to be heavily regulated sectors. For those that do undergo the process, they face the risk of their submissions becoming heavily outdated by the time a decision is received, due to the rapidly moving business environment that start-ups often operate in.

[48] https://waterinnovation.challenges.org/water-discovery-challenge/what-you-can-win/

Regulators should consider mechanisms to increase efficiency in their processes to bring down waiting times. One way of doing this is for a regulator to allow and encourage companies to engage at an early stage. The regulator may be able to assist in accelerating consideration of what safety studies should be undertaken (and what might not be necessary), and early consideration of resulting data, before the final stage of formal scrutiny and approval.

Another way to do this is through leveraging a trusted relationship between companies and regulators. One mechanism for this is where information about, for example, a company's quality system, need not be repeated every time a new iteration of a product is produced, hence saving duplication of processes and compliance accreditation.

The system for aviation safety is one example of collaboration (known in the sector as Performance-Based Regulation, based on an 'open and just culture'). This collaborative model has operated effectively for 25 years, achieving the outcomes of safe flight. A further recent example of collaboration is a pilot being run by the Food Standards Agency with a number of supermarkets, with the aim of avoiding unnecessary duplication of inspections and compliance checks.[49] A benefit for the regulator is to reduce time-consuming but unnecessary inspections on supermarkets, thereby freeing resources for engaging with smaller retailers and businesses. These models are examples of a trend towards Outcome-Based Collaboration.[50]

Another potential solution to this challenge is regulators adopting more data driven approaches to triage and automate requests. Our *Drones Report* found that such an approach was one of the key reasons for success in pioneering commercial deployment of drones in countries as diverse and unrelated as Rwanda, Singapore, Switzerland, and Ukraine.[51] Such a shift in approach will require significant investment and research to ensure safety and protection, but will be important for regulators to keep pace with increasing demand.

If it is deemed unfeasible to bring down wait times, regulators should at least consider iterative approaches to undertaking assessments of regulatory approval or authorisation. Whilst this may not reduce the total time taken to reach a decision, it can greatly help to de-risk the process of undertaking approval through providing opportunities for the organisation to correct errors or amend its processes in response to feedback from the regulator.

[49] Further information available at: https://www.food.gov.uk/research/evaluation-of-food-standards-pilot-introduction#:~:text=The%20ABC%20programme%20aims%20to,which%20pose%20the%20greatest%20risk

[50] C. Hodges, Outcome-Based Cooperation (Hart, 2022).

[51] RHC (2021): Regulatory Horizons Council: the regulation of drones. Available at: https://www.gov.uk/government/publications/regulatory-horizons-council-the-regulation-of-drones

We welcome the Department for Business and Trade's proposals to encourage regulators to set approval time targets as part of its ongoing consultation on the growth duty.[52] This is an important step to allow greater scrutiny of the impacts of regulation on innovation, as we discuss next.

[52] https://www.gov.uk/government/consultations/smarter-regulation-regulating-for-growth

Measuring the impact of regulatory approaches on innovation

What we have set out above reveals considerable opportunities for delivering innovation not only as fruits of science and technology but also in regulatory systems and practices. Indeed, we think that changing the latter is imperative for achieving the former. There is also a wealth of examples of this already arising, as our case studies demonstrate. What is missing is a holistic understanding of what works in different technology applications, and the impacts on the early business community. We need to put in place resources to evaluate regulatory interventions, monitor progress and adapt our approach accordingly. Leading regulators are developing the capture of more data *from or about* regulatees but this could be extended to evaluate the regulatory *system* and *technique* that is being used. This could be facilitated by an annual national innovation regulation survey to gather and evaluate relevant information at a national, organisational, regional, and local level across different sectors to inform an annual report on progress and best practice.

This should include evaluation of:

a) Regulatory impacts on innovation and smaller businesses – at minimum: average waiting times; and numbers of applications and approvals.
b) Effectiveness of pro-innovation initiatives e.g. 'sandboxes', including uptake amongst SMEs.

Effective evaluation also depends on us having an agreed set of coherent good regulatory outcomes that we are hoping to achieve, such as delivering safety and protection, fair markets, or innovative products and services into thriving markets. Regulators are typically subject to legal duties, but these rarely if ever include focusing on delivering outcomes. The delivery of desirable outcomes requires coordination between all those who are affected by success, risk or harm. Such coordination and involvement points towards realignment of methods of engagement and collaboration for all stakeholders in agreeing what needs to be done, how it should be done, and how it is being performed.

Recommendation 3: Government and regulators should continue to build the knowledge base on pro-innovation regulation, and particularly the impacts on start-ups and scaleups.

Options to implement this should be developed by policy teams and regulators, but could include:

- **Encouraging regulators to evaluate the effectiveness of pro-innovation measures, such as sandboxes, on early-stage businesses, and share learnings systematically through the Regulators' Innovation Network.**

- **Ensuring that regulatory expertise is represented in the new Scaleup Forum, to enable it to act as a bridge to strengthen Government's understanding of regulatory impacts on the early-stage business community.**

- **Establishing more consistent and comprehensive monitoring of regulatory impacts on innovation, for example through an annual innovation review, which could bring together metrics on regulatory approvals, waiting times, and small business participation in regulatory experimentation initiatives.**

Conclusion

Throughout this work we have aimed to distil the reasons why innovative start-ups and scaleups can be particularly challenged by regulations that are not designed with innovation in mind. As seen through the stories of three start-ups, these challenges can occur for a number of reasons, and businesses may find themselves facing a combination of these scenarios, stacking the odds against them.

As we outline, there are many ways that regulators, Government and other stakeholders can work together to better support innovation and early-stage businesses, and many examples where this is already happening. But a joined-up systems approach is needed to ensure the successful delivery of such measures. Our three recommendations highlight areas of change that can help catalyse such a shift:

Further, in our view, the *culture* and *motivation* of those involved in designing and delivering regulation are critical factors in whether they are achieved and at what pace. Challenging as subjects such as culture are to affect and influence, they are of fundamental importance. We intend to explore issues of culture with regulators, and how pro-innovation cultures can be supported and sustained, in upcoming work.

We believe that there are many reasons to be hopeful. The UK's business-friendly regulatory regime is already one of the least burdensome – and most pro-innovation – in the world according to the OECD.[53] Supporting our cutting-edge start-ups and scaleups will only help to further strengthen this and ensure that the UK remains competitive in the face of increasing global technology development.

[53] (2021) OECD Regulatory policy outlook 2021 | EN | OECD. Available at: https://www.oecd.org/gov/oecd-regulatory-policy-outlook-2021-38b0fdb1-en.htm

Annex A: summary of the RHC's evidence gathering roundtable

Monday 12th June 2023

The Regulatory Horizons Council (RHC) convened innovators and thought leaders in regulation (participants listed below) as part of London Tech Week to discuss the role that regulation plays in supporting start-ups to scale their products in the UK.

Background

The RHC is an independent expert committee that identifies the implications of technological innovation, and provides government with impartial, expert advice on the regulatory reform required to support its rapid and safe introduction.

The RHC published a cross-cutting report last year on Closing the Gap; getting from Principles to Practice for innovation friendly regulation. The report made a number of recommendations to government.

The Council has initiated a programme of work to convene key stakeholders to explore important themes highlighted in the report and develop actionable next steps. One of the areas that this work is addressing is the role of regulation in supporting the scaleup of innovations in the UK.

To contribute to this work, the roundtable invited attendees to share their views on:

a) Areas where regulation can act as an enabler or a barrier to innovative start-ups looking to scale their products in the UK;
b) Actions that Government and regulators can take to create a regulatory framework and innovation ecosystem that is more supportive to start-ups.

Participants' views will be used to inform the RHC's report and actions for Government, due to be published later in the year. **This note summarises the key themes that arose during the discussion.**

Key themes

Engagement between regulators and start-ups

Participants raised that many start-ups struggle to approach the regulatory system, not knowing who to talk to and how to engage most effectively. There may also be an element of nervousness around approaching a regulator due to cultural perceptions. It was suggested that one of the most impactful activities that regulators could take to support start-ups is making themselves accessible to innovators, such as in the form of open 'office hours'.

The important role of intermediary organisations in facilitating engagement with regulators was discussed, but it was noted that this is not a substitute for direct engagement,

Regulatory understanding of emerging business models

There is a need to ensure that regulators understand the unique challenges faced by SMEs. Encouraging closer engagement, e.g. office hours as discussed above, could go some way to help address this, but consideration should be given to broader regulatory culture and organisational structure. It was suggested that Boards of regulators should contain individuals who have knowledge and experience operating in start-ups.

A further, connected issue was raised around ensuring that regulators have the technological expertise to anticipate regulatory issues arising from rapid technological innovation. It was agreed that representation within regulators of innovative SME's will support regulators to have access to the cutting-edge technological expertise, which may not be possible through relying on expertise of incumbents.

There was also some discussion of the benefits of regulators employing digital tools and databases, to enable them to work more collaboratively with innovators to address issues and harms.

Pro-innovation mandate for regulators

It was recognised that part of the cultural misalignments that are present between start-ups (operating in a high-risk environment) and regulators (typically risk-averse) is due to a lack of a pro-innovation mandate on regulators whose primary role is to ensure safety. Some mechanisms to address this were discussed, such as a potential role for the liability system or avenues for political intervention where there is a need for a more risk tolerant approach.

Resource

It was also recognised that the shift towards a precautionary to a proportionate regulatory approach will require a substantial shift in regulatory approaches and behaviours, which will be challenging for regulators who are already resource-constrained bellowing Brexit.

It was suggested that Government set out the return-on-investment case, to justify a need for increased funding and resource for regulators to promote innovation.

Regulatory coordination

It was highlighted that start-ups working in sectors that span multiple regulators are likely to face increased challenges. It was explored whether there could be mechanisms for mutual recognition of regulatory decisions taken, where applicable to avoid needing to gather multiple approvals for shared regulatory requirements. This could be supported by efficient data sharing mechanisms between regulators. Initiatives such as the DRCF[54] and the AI and Digital Regulations Service[55] were welcomed as a step in the right direction, but it was recognised that there is a need to expand this across further sectors.

Sandboxes, scaleboxes and testbeds

Sandboxes were highlighted as an important experimental regulatory initiative that can support start-ups to scale. However, there were a number of limitations and considerations raised towards their effectiveness:

- Whilst useful in helping innovators to navigate the regulatory system, their ability to change regulatory approaches was questioned;
- There may be inconsistency in which innovators gain access to the system;
- There needs to be adequate mechanisms for innovators to leave the sandbox and scale their products; and
- The FCA sandbox is widely recognised as a success, but sectoral differences mean it may be difficult to emulate its success in other areas – more research is needed into the different environments where sandboxes are effective.

In light of the challenges raised, there was a shared recognition that sandboxes offer the opportunity to add value but need to be deployed in the right way (tailored to the sector in question) with adequate resourcing and cultural buy in from the regulator. The importance of fostering an open and honest culture towards failures when implementing experimental regulatory was also discussed.

[54] https://www.gov.uk/government/collections/the-digital-regulation-cooperation-forum
[55] https://www.digitalregulations.innovation.nhs.uk/

Participants also discussed the role of large-scale demonstration and testing facilities (for example through freeports) for innovators moving beyond proof of concept to operation at scale. There was some discussion of the role of liability and indemnity to facilitate experimentation at scale.

Supportive data infrastructure and data sharing

The importance of having readily available, high-quality datasets was discussed as an enabler to innovative start-ups. An example raised was the rise of open banking data, and it was also noted that in the life sciences space such as in medical device development having regulated access to data is fundamental to demonstrate product safety. It was highlighted that some of the value that derives from sandboxes is data access.

Government Chief Scientific Adviser (GCSA) Review of Pro-innovation Regulation of Emerging Technologies

Participants acknowledged and welcomed the ongoing GCSA review of regulation for innovation, including a paper on crosscutting issues.[56] The importance of timely implementation of its recommendations was noted.

Attendees present

Chair: Professor Christopher Hodges OBE, Chair of the Regulatory Horizons Council

- **Camilla de Coverly Veale**, Policy Director at Startup Coalition
- **Dr Ian Brotherston**, Head of Government Levers at Innovate UK
- **Irene Graham OBE**, CEO of the ScaleUp Institute
- **John Fingleton CBE** Founder and CEO of Fingleton
- **Leo Ringer**, Founding Partner at Form Ventures
- **Phillip Salter**, Founder of The Entrepreneurs Network
- **Sarah Hunter**, Board Member at the Advanced Research and Invention Agency
- Officials from the Department for Science Innovation and Technology

[56] https://www.gov.uk/government/publications/terms-of-reference-for-the-review-of-regulation-for-emerging-technologies/pro-innovation-regulation-of-technologies-project-terms-of-reference