

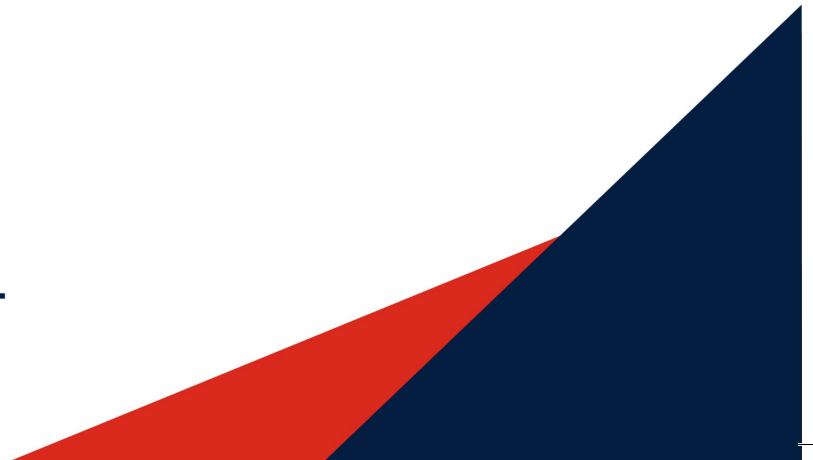


HM Government

Regulation for the Fourth Industrial Revolution

White Paper

June 2019
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Regulation for the Fourth Industrial Revolution

Presented to Parliament
by the Secretary of State for Business, Energy and Industrial Strategy
by Command of Her Majesty

June 2019



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ISBN 978-1-5286-1362-0
CCS0619346774 06/19

Printed on paper containing 75% recycled fibre content minimum.

Printed in the UK by the APS Group on behalf of the Controller of Her Majesty's Stationery Office.

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Foreword

The world is changing faster than ever. New technology is creating new industries, changing existing ones and transforming the way things are made. We need a more agile approach to regulation, that supports innovation while protecting citizens and the environment.

We are a nation of innovators. Throughout our history we have seized the opportunities to create a better future for ourselves. In the First Industrial Revolution, British engineer Thomas Savery's pump paved the way for industrial use of steam power. In the Second, British scientist Michael Faraday's electromagnetic rotary devices formed the basis for practical electricity use. In the Third, British computer scientist Tim Berners-Lee invented the World Wide Web.

Technological breakthroughs in areas from artificial intelligence to biotechnologies are now heralding a Fourth Industrial Revolution, with the power to reshape almost every sector in every country. Our Industrial Strategy positions the UK to make the most of this global transformation.

Our regulatory system is second to none, as recognised by the Organisation for Economic Cooperation and Development's Regulatory Policy Outlook in 2018. It protects citizens and enables business to thrive. Together with our global research prowess, world-class universities and open, competitive markets, it attracts firms to innovate and invest in the UK. As the Fourth Industrial Revolution changes the way we live and work, it is vital that our regulatory system keeps pace.

This White Paper sets out our plan to maintain our world-leading regulatory system in this period of rapid technological change. We will support and stimulate new products, services and business models, with greater space for experimentation. We will uphold safeguards for people and the environment and engage the public in how innovation is regulated. And we will maintain the stable, proportionate regulatory approach the UK is rightly known for.

Our openness to technology and innovation continues as we leave the European Union. This White Paper is our plan to secure our success.

Rt Hon Greg Clark MP

Secretary of State for Business, Energy and Industrial Strategy

Championing innovation

We need to take action to maintain our world-beating regulatory system and realise the potential of the Fourth Industrial Revolution.

The Fourth Industrial Revolution

The Fourth Industrial Revolution is of a scale, speed and complexity that is unprecedented. It is characterised by a fusion of technologies – such as artificial intelligence, gene editing and advanced robotics – that is blurring the lines between the physical, digital and biological worlds. It will disrupt nearly every industry in every country, creating new opportunities and challenges for people, places and businesses to which we must respond.

Our modern Industrial Strategy seeks to put the UK at the crest of this global wave of technological innovation, bringing the benefits to business and consumers alike. Our foundations are strong. The UK ranks in the top five in the Global Innovation Index¹. We are a global leader in science and research and home to four of the top 10 universities in the world². We have a thriving start-up environment and are home to many of the world's most R&D-intensive businesses. We develop and attract some of the most talented people in the world.

We want to build on our strengths in developing and deploying ideas to become the world's most innovative economy. We want to raise our total investment in R&D to 2.4 per cent of GDP by 2027, the biggest increase on record. We have set four Grand Challenges for the UK government and wider economy to seize the opportunities presented by the Fourth Industrial Revolution.

The Industrial Strategy Grand Challenges

1. We will put the UK at the forefront of the artificial intelligence and data revolution.
2. We will maximise the advantages for UK industry of the shift to clean growth.
3. We will become a world leader in shaping the future of mobility.
4. We will harness the power of innovation to help meet the needs of an ageing society.

Our regulatory system is a national asset. We are ranked 9th among 190 economies for the ease of doing business in the UK³, with the quality of our regulatory practices given the highest overall country score by the Organisation for Economic Co-operation and Development (OECD)⁴. We protect the natural environment and ensure the safety and employment rights of citizens. We also provide the certainty needed for businesses to thrive.

The Fourth Industrial Revolution presents challenges for regulatory systems across the globe, as they struggle to keep pace with rapid, complex technological innovation. In our Industrial

¹ Cornell University, INSEAD and the World Intellectual Property Organization (2018).

² QS Top Universities (2019).

³ World Bank (2019).

⁴ OECD (2018).

Strategy, we committed to develop an agile regulatory approach that supports innovation and protects citizens and the environment. We need to act now to maintain our world-beating regulatory system in this period of transformational change.

Evolving our regulatory model

Innovation – the development of new ideas, new ways of doing things, new products and services, new technologies and new business models – is crucial to improving the productivity of our economy and solving our most pressing social and environmental challenges.

Innovation is at the heart of our Industrial Strategy. It can drive the creation of new sectors, such as the quantum technology industry that is expected to be worth £1 billion to the UK in future⁵. It can help us find new ways of diagnosing and treating diseases or novel approaches to cutting carbon emissions and tackling climate change. It can give consumers greater choice and lower prices through greater competition. We need to seize the opportunities that innovation presents for our economy and citizens alike.

Understanding regulation

Regulation describes the rules that are set out in legislation and the processes used to monitor and enforce them. It complements other government levers such as taxation and public spending in shaping our economy. While some regulation relates to citizens, this paper is focused on the impact of regulation on business.

The government regulates business to deliver better outcomes for the economy, society and the environment – for example to safeguard citizens' privacy, protect wildlife from pollution or uphold consumer rights. But where regulation is poorly designed, it can inhibit productivity.

The government strives to ensure that regulatory interventions are proportionate, targeted, fair and transparent. It ensures that alternatives to regulation (such as voluntary standards or incentives) are considered before regulation is introduced, and that regulation is regularly reviewed to minimise unnecessary burden to business.

Regulation has a powerful impact on innovation. It can stimulate ideas and can block their implementation⁶. It can increase or reduce investment risk – and steer funding towards valuable R&D or tick-box compliance⁷. It can influence consumer confidence and demand – and determine whether firms enter or exit a market⁸.

We need to reshape our regulatory approach so that it supports and stimulates innovation that benefits citizens and the economy. At present, only 29% of businesses believe that the government's approach to regulation facilitates innovative products and services being efficiently brought to market⁹. The need for reform is urgent: 92% of businesses from a range

⁵ UK National Quantum Technologies Programme (2015).

⁶ Ambec et al (2013), Stewart (2010), Pelkmans and Renda (2014).

⁷ Pelkmans and Renda (2014), Stewart (2010), Blind (2012).

⁸ BERR (2008), Blind (2012), OECD (2012).

⁹ BEIS (2018a).

of sectors think they will feel a negative impact if regulators don't evolve to keep pace with disruptive change in the next two to three years¹⁰.

Other countries are rapidly reforming their regulatory environments to support future innovation, with Nesta describing these anticipatory approaches as 'an increasingly important source of competitive advantage in the global economy'¹¹. By taking an anticipatory approach we can give people faster access to innovations that can transform their lives and attract the ideas, talent and investment to the UK that will drive our future prosperity.

We are turning things round. The Financial Conduct Authority's regulatory sandbox (p.19) has kick-started a wave of regulator-led initiatives to support new products and services to come to market and been widely emulated across the globe. Our Regulators' Pioneer Fund is accelerating the change, with £10 million invested in 15 projects to support technologies from autonomous shipping to virtual lawyers. We have established a partnership with the World Economic Forum to shape the global governance of technological innovation.

But we can go further. The Business Secretary has established a Ministerial Working Group on Future Regulation to drive reform across government to put us at the forefront of the industries of the future. The Prime Minister's Council for Science and Technology has provided recommendations on how to enhance the regulatory oversight of technological innovation. We have identified six challenges we need to address:

- We need to be on the front foot in reforming regulation in response to technological innovation
- We need to ensure that our regulatory system is sufficiently flexible and outcomes-focused to enable innovation to thrive
- We need to enable greater experimentation, testing and trialling of innovations under regulatory supervision
- We need to support innovators to navigate the regulatory landscape and comply with regulation
- We need to build dialogue with society and industry on how technological innovation should be regulated
- We need to work with partners across the globe to reduce regulatory barriers to trade in innovative products and services

This White Paper sets out our plan to tackle these six challenges and seize the opportunity presented by the Fourth Industrial Revolution. We want to lead the world in innovation-friendly regulation that supports the emergence of new products, services and business models for the benefit of all. The White Paper will be matched later this year with papers describing how we will modernise consumer and competition regulation in response to the transformation in our economy.

¹⁰ PA Consulting (2018).

¹¹ Nesta (2019)

Facing the future

We will back the early introduction of innovation to put the UK at the forefront of the industries of the future.

The case for change

As we enter the Fourth Industrial Revolution, a wave of technological innovation is creating new industries, disrupting existing ones and transforming the way things are made. New products, services and business models are emerging which don't fit with existing regulatory systems.

The rate of innovation frequently exceeds the speed at which regulatory systems can adapt. Furthermore, innovation increasingly blurs the lines between sectors and cuts across traditional regulatory boundaries. The result is that businesses may face unnecessary obstacles in bringing forward new propositions, while citizens are left with outdated protections¹². The benefits of innovation for people and the economy can be lost.

In our modern Industrial Strategy, we committed to develop a new, agile approach to regulation that supports innovation while protecting citizens and the environment. We will identify where regulation needs to evolve and back the early introduction of innovation to put the UK at the forefront of the industries of the future.

Backing transport innovation through the Future of Mobility Grand Challenge

We are witnessing a global transformation in how people, goods and services move around, powered by technological advances in areas such as automation, electrification and data.

The UK is well placed to seize the benefits of this transformation. We have significant strengths in many of the most relevant areas of research and development, including artificial intelligence and complex vehicle engineering. We have dynamic businesses developing new mobility solutions, and innovative, strong and diverse automotive, rail, maritime and aviation sectors. Our regulatory environment must evolve to support these industries in developing new technologies and business models.

Our Future of Mobility Grand Challenge is paving the way. To help policymakers identify the choices and trade-offs to come – and to grasp the exciting opportunities in this area – the Government Office for Science has prepared a foresight report. The report examines trends to 2040 and identifies priority areas for government to consider.

¹² Wellcome Trust (2019)



The report informs work by the Department for Transport to establish a flexible regulatory framework to encourage new modes of transport and new business models. The Future of Mobility Regulatory Review will be one of the most significant of its sort for many years, asking fundamental questions about how we regulate transport in the UK.

We are already reviewing regulations in four relevant areas: zero emission vehicles, automated vehicles, drones and future flight, and maritime autonomy. Alongside this, reviews have been initiated in the following areas:

- Micromobility vehicles, and how to trial them
- Facilitating mobility as a service
- Sharing transport data
- Modernising bus, taxi and private hire vehicle legislation

The aim is to ensure the UK's thriving mobility sector has the innovative and flexible framework it needs – one that promotes safety and active and accessible travel, while providing certainty for investment and the space for invention and trials.

Our plan

Our ambition is to be the world's most innovative economy and the best place to start and grow a business. We want to give businesses confidence to develop and adopt 'world firsts' here in the UK, supported by enabling regulatory frameworks that provide clarity on the outcomes the government and society expect.

We will establish a Regulatory Horizons Council to identify the implications of technological innovation and advise the government on regulatory reform needed to support its rapid and safe introduction. The Council will:

- Scan the horizon for technological innovation and trends, building on existing work and data across government;
- Work with innovators, civil society, regulators and others to identify high-potential products, services and business models and the broad implications for people, business and the environment; and
- Advise government on broad priorities for regulatory reform in order to facilitate the rapid and safe introduction of emerging products, services and business models.

The government's response may include the introduction, adaptation or repeal of regulation, or the adoption of alternatives to regulation (such as voluntary standards), depending on the nature of the innovation.

Maximising the potential of data-driven technologies: the Centre for Data Ethics and Innovation

The use of data and artificial intelligence (AI) is set to enhance our lives in powerful and positive ways. Our AI and Data Grand Challenge seeks to maximise its potential. We want the UK to be at the forefront of global efforts to harness data and artificial intelligence as a force for good.

For this, businesses need clear rules and structures that enable safe and ethical innovation in data and AI. Advances in the ways we use data are giving rise to new and sometimes unfamiliar economic and ethical issues, such as how AI might be used to influence the information and choices available to us. We need to make sure we have the right governance in place to address these rapidly evolving issues, otherwise we risk losing confidence amongst the public and holding businesses back from valuable innovation.

In response, we have established the new Centre for Data Ethics and Innovation to identify the measures needed to strengthen and improve the way data and AI are used and regulated. This will include articulating best practice and advising on how we address potential gaps in regulation.

The Centre acts as the authoritative source of advice to government on the governance of data and AI and complements the new Regulatory Horizons Council, which will look more widely across the economy as a whole.

The Council will prepare a **regular report to government on innovation across the economy, with recommendations on priorities for regulatory reform** to put the UK at the forefront of the industries of the future. The government may also commission the Council to prepare 'deep dive' reports into the regulatory implications of specific areas of innovation.

The Council's recommendations will be considered by the **Ministerial Working Group on Future Regulation**, chaired by the Business Secretary, and published by the government. The Ministerial Working Group will oversee a joined-up government response, ensuring that innovations are not hindered by the complex division of responsibilities across government departments and regulators.

The Council will be an independent panel with expertise in regulation and innovation in different domains of the economy. It will operate as an advisory committee and be supported by civil servants. It will complement and draw upon existing horizon-scanning activity across

government – including the work of the Council for Science and Technology and Government Office for Science – and drive improvements in horizon-scanning for regulatory change by departments and regulators. It will collaborate closely with sector councils in order to advise the government on economic opportunities.

The Council will dovetail with the wider regulatory landscape by making recommendations to government on what reforms should be prioritised to support the rapid and safe introduction of technological innovation. It complements expert bodies, such as the Centre for Data Ethics and Innovation, which make detailed, specialist recommendations on how to take forward reform. It also complements the role of the Better Regulation Executive, which supports departments and regulators in considering how to design and deliver regulation, and the Regulatory Policy Committee, which scrutinises the quality of evidence and analysis used to inform regulatory proposals.

We are delivering record increases in public sector R&D investment, as part of our ambition to raise total investment in R&D to 2.4 per cent of GDP by 2027. The Council will work closely with UK Research and Innovation to facilitate the safe introduction of innovations backed by publicly-funded schemes such as the Industrial Strategy Challenge Fund.

Harnessing technology to support the prevention, early diagnosis and treatment of chronic diseases

Using AI and data, there is an opportunity to accelerate medical research in early diagnosis, leading to better prevention and treatment of disease. Within 15 years better use of AI and data could result in over 50,000 more people each year having their cancers diagnosed at an early rather than late stage¹³.

The Prime Minister has announced a mission to put the UK at the forefront of the use of AI and data in early diagnosis, innovation, prevention and treatment as part of the AI and Data Grand Challenge. Seizing this opportunity could save lives and lead to a whole new industry of diagnostic and tech companies.

The government is working with the NHS and regulators across the health and social care system to develop regulatory guidance for innovators looking to bring novel medical technologies to market. The project is engaging with industry, clinicians and patients to consider how data should be handled and ensure any new frameworks support a strong business environment.

In tandem, the Medicines and Healthcare Products Regulatory Agency is developing synthetic datasets for innovators to validate algorithms and artificial intelligence used in medical devices, backed by investment through the Regulators' Pioneer Fund. Findings from both projects will help inform future regulatory reform to support these technologies to emerge.

¹³ Cancer Research UK (2014).

Focusing on outcomes

We will create an outcome-focused, flexible regulatory system that enables innovation to thrive while protecting citizens and the environment.

The case for change

Reforming regulation in response to technological innovation will only take us so far. We also need to look at how to make legislation that enables innovation and is resilient to future change. Just 29% of businesses believe that the government's approach to regulation supports them in bringing new products and services to market¹⁴.

Prescriptive legislation can provide clarity for businesses today but in the longer term can lock in outdated approaches to achieving policy outcomes and hinder innovation¹⁵. It is poorly suited to the complex settings – with a range of actors and fast-paced technological change – that characterise the Fourth Industrial Revolution. At worst, it can divert funds from investment to 'tick box' compliance without providing adequate safeguards for society.

Outcome-focused, 'tech-neutral' legislation involves a focus on the achievement of 'real-world' outcomes for citizens and the environment. It increases flexibility for business on how they can achieve those outcomes, enabling them to find the most efficient way to comply and reducing costs for consumers. It can encourage innovation since firms have greater freedom to try out new ideas, technologies, business models and practices¹⁶.

It can also encourage businesses to think more carefully about how best to achieve a regulatory goal, and not mechanically follow rules laid out by the regulator. It can also give regulators greater flexibility in how they use their powers to achieve the best outcomes for citizens and the environment. It can enhance stability and predictability for business, as public policy goals are set for the long-term.

Where challenging outcomes are set, legislation can actively drive innovation that delivers benefits for citizens and the environment as businesses develop novel approaches to achieve compliance¹⁷. In domains such as the energy, automotive and waste industries, regulation plays a powerful role in shaping the market for innovation.

Supporting the emergence of smart systems

Our energy system is changing rapidly. There is more low carbon generation, such as power from solar and wind, which produces different amounts of electricity depending on the weather. It is increasingly decentralised, with generation and batteries located in or near people's homes and businesses.

¹⁴ BEIS (2018b).

¹⁵ BEIS (2018a).

¹⁶ Stewart (2010), Pelkmans and Renda (2014).

¹⁷ Ambec et al. (2013).

New technologies such as electricity storage, smart heating controls and electric vehicles are emerging which can be used to help balance the electricity system. However, our regulatory system was not developed with these new technologies in mind.



As laid out in the Smart Systems and Flexibility Plan, developed jointly with the energy regulator Ofgem, we are working to develop a best in class regulatory framework that supports these innovations. We are working with industry to reform markets, legislation, licences, codes and standards.

The drive towards a smart and flexible energy system is an important tenet of the government's Clean Growth and Industrial Strategies. The changes promise to provide significant public benefits, from lower energy bills to cleaner air and lower carbon emissions. By 2050, a smarter and more flexible system could save the UK £17-40 billion¹⁸.

Businesses need clarity on whether their propositions will comply with legislation in order to have confidence to invest. Regulatory guidance, codes of practice and industry standards should be used to complement outcome-focused legislation and provide clarity for business. These tools can more easily keep pace with technological change and be more accessible and less burdensome than prescriptive legislation.

Voluntary standards can play an important role in enabling and stimulating innovation – from supporting the dissemination of ideas to facilitating access to markets¹⁹. While often more agile than regulation, they can also face challenges in keeping pace with technological innovation²⁰. It is important that standards are developed and reviewed in a timely and inclusive way, with innovators at the heart of the process.

¹⁸ Carbon Trust and Imperial College London (2016).

¹⁹ DTI (2005), Blind (2013), BIS (2012), Riillo (2009).

²⁰ Blind (2013), Featherston et al (2015).

Accelerating the introduction of self-driving vehicles

The Centre for Connected and Autonomous Vehicles (CCAV) is overseeing a groundbreaking programme to prepare the UK's regulatory framework for self-driving vehicles ahead of their introduction on UK roads. It has developed an open regulatory approach that safeguards citizens and supports the development of the technology as it evolves.

This includes the recently updated world-leading Code of Practice for testing automated vehicles. Testing any level of automated vehicles on public roads is possible, provided they comply with the law, including having a driver, in or out of the vehicle, a roadworthy vehicle, and appropriate insurance. The recent update to the Code announced that the government would introduce an application process for more advanced trials. This will facilitate the development of the technology, without the need for repeated changes to regulation.



CCAV is leading the charge in considering the wider implications of the introduction of self-driving vehicles. It has introduced legislation to insure the use of self-driving vehicles through the Automated and Electric Vehicles Act 2018, so that victims of collisions get quick and easy access to compensation. It has asked the Law Commission of England and Wales and the Scottish Law Commission to undertake a joint regulatory review to identify further legal obstacles to the widespread introduction of self-driving vehicles. This project is consulting widely and will provide a final report in 2021.

CCAV is also working with the British Standards Institution to deliver a programme of standards to help accelerate development and deployment of self-driving vehicles. The programme seeks to address public safety and reliability concerns and supports the UK's reputation as a centre of excellence for vehicle testing, design and manufacturing.

CCAV's programme has helped to put the UK at the forefront of this emerging industry and, with the Department for Transport, given the UK lasting influence in international debates on the regulation of automated vehicles.

Our plan

We will create an outcome-focused, flexible regulatory system that enables innovation to thrive while protecting citizens and the environment. We will match this with clarity for business through better use of regulatory guidance, codes of practice and industry standards.

We will pilot an innovation test so that the impact of legislation on innovation is considered as we:

- develop and assess policy options;
- consult and engage on policy proposals;
- design, introduce and implement legislation; and
- monitor, evaluate and review legislation.

We will encourage policymakers to consider the governance of innovation in a holistic way, noting the role that alternatives to regulation can play in providing government, citizens and businesses with assurance. We will encourage policymakers to reflect on when the right time is to introduce regulation²¹.

Our approach will encourage policymakers to focus on real-world outcomes, with legislation that provides flexibility for experimentation and adaptation. Prescriptive regulatory requirements would only be set out in legislation where necessary to provide important protections. Where possible, alternative approaches such as statutory guidance will set out requirements so that as technology changes the system can respond in a timely and flexible manner.

We will develop tools for policymakers to support them to consider these issues; we will also develop improved analytical methods to capture the impact of regulation on innovation. During the pilot, we will invite the Regulatory Policy Committee to scrutinise the application of the innovation test, to ensure that innovators have confidence in how government is developing significant new regulatory legislation.

Making the UK the safest place in the world to be online

The internet is a powerful force for good. Combined with new technologies such as artificial intelligence, it is changing society perhaps more than any previous technological revolution – growing the economy, making us more productive, and raising living standards.

Alongside these new opportunities come new challenges and risks. The internet can be used to spread terrorist material; it can be a tool for abuse and bullying; and it can be used to undermine civil discourse, objective news and intellectual property. As set out in our Digital Charter, we are committed to making the UK both the safest place to be online and the best place to start and grow a digital business.

In April, the Department for Digital, Culture, Media and Sport and the Home Office published a White Paper to tackle a range of both legal and illegal harms, from cyberbullying to online child sexual exploitation. In keeping with our ambition to lead the

²¹ Tait et al (2017)

world in innovation-friendly regulation that encourages the tech sector and provides stability for businesses, the White Paper sets out an outcomes-focused legislative approach that will support future technological change.

We will promote new ways to trigger when post-implementation reviews of legislation are undertaken to ensure that legislation does not languish on the statute books and inadvertently 'lock in' outdated technologies or approaches. We will pilot new requirements for government departments on how they should monitor and evaluate the impact of legislation on innovation. In addition, we will consider the role of scrutiny in developing the content of monitoring and evaluation plans for significant new regulation before it is made law.

We will develop tools for regulators to support them to review their guidance, codes of practice and other regulatory mechanisms to ensure that they provide flexibility for those businesses that want to innovate, while ensuring a clear route to compliance for other businesses. **We will support business, policymakers and regulators to make effective use of standards where appropriate** as a complement to more outcome-focused legislation.

We will invite the Office for Product Safety and Standards, British Standards Institution, National Physical Laboratory and UK Accreditation Service to set out their vision for how the development and review of standards should evolve as we enter the Fourth Industrial Revolution. We will ask them to consider how standards can be developed and reviewed in an agile way that keeps pace with technological innovation and draws in the voice of innovators and disruptors.

Supporting experimentation

We will enable greater experimentation, testing and trialling of innovations under regulatory supervision to support and stimulate the breakthrough of new technologies.

The case for change

Regulators have a powerful impact on business innovation. Over 60% of businesses consider that regulators' approaches affect how willing they are to invest in innovation and how efficiently they can bring innovations to market²².

A new approach is needed to attract more investors and innovators to the UK and to support businesses to thrive in the Fourth Industrial Revolution. 92% of businesses across a range of sectors think they will lose revenue if regulators don't keep pace with disruptive change in the next two to three years²³. A number of regulators are adapting their approach.

Realising the power of financial technologies

From AI to blockchain, data-driven financial technologies (FinTech) are changing the way that we bank, invest, insure and even pay for things. The UK's FinTech sector is booming, underpinned by our world-leading financial services sector and thriving tech scene.

In 2016, the Financial Conduct Authority seized the initiative to support this emerging industry by establishing the world's first 'regulatory sandbox': a safe space where firms can work with the regulator to trial innovative products, services and business models with consumers without having to meet all the usual requirements for compliance.

Since its establishment, the sandbox has received more than three times as many applications than places available. Access to the sandbox has helped reduce the time and cost of getting innovative ideas to market (in the first year, 90% of firms progressed towards wider market launch) and improve access to finance (40% received investment during or following their sandbox tests)²⁴.

FinTech firm Asset Hedge introduced a web-based platform offering forex options to assist small businesses and individuals to protect against losses incurred because of currency fluctuations. They successfully completed the sandbox programme to become a fully regulated company. Assure Hedge founder and chief executive Barry McCarthy said:

"We have effectively been given the same regulation that large banks have, so it really allows us to compete with the big players."

²² BEIS (2018a).

²³ PA Consulting (2018).

²⁴ Financial Conduct Authority (2017).

It's not just business that benefits. Consumers benefit from new products which have better safeguards built in up front, while the regulator benefits from greater insight into technological innovation. The model has been emulated by more than 20 countries across the globe and translated to sectors from health to transport.

Regulators from Ofgem to the Civil Aviation Authority have built on the Financial Conduct Authority's model to launch similar initiatives. Other organisations, such as the Competition and Markets Authority, are actively stimulating innovation by driving sharing of data which enables disruptors to enter new markets and deliver better outcomes for all.

Our Regulators' Pioneer Fund has sought to accelerate this change: investing £10 million in 15 regulator-led initiatives to support propositions from autonomous ships to AI-led medical diagnostics to come to market. But further action is needed to bolster regulator capacity and capability to support the transformative innovation of the Fourth Industrial Revolution.

Our plan

Regulators should play an active role in supporting the innovation economy. We want to enable greater experimentation, testing and trialling of innovations under regulatory supervision to support and stimulate the breakthrough of new technologies.

The Regulators' Pioneer Fund is being piloted from 2018 to 2020, supported by an independent evaluation of the impact on innovation. **We will examine the case for extending the Regulators' Pioneer Fund in future to help regulators to keep pace with technological innovation** and enable the emergence of new products, services and business models.

Many regulatory functions are performed at a local level, from taxi licensing to trading standards. **We will examine the case for extending the Regulators' Pioneer Fund to local authorities in future, in order to help them support greater testing and trialling of innovations in their area.**

From smart shipping to AI-powered legal services

The Regulators' Pioneer Fund is backing the Future of Mobility and AI and Data Grand Challenges through ground breaking projects to enable technologies from smart shipping to AI-powered legal services.

The Solicitors Regulation Authority has already taken steps to facilitate innovation in the legal industry, inviting firms to develop new business models in a controlled way. The Regulators' Pioneer Fund investment will enable the Solicitors Regulation Authority to work with the innovation foundation Nesta to accelerate ethical AI-powered innovations, with a focus on legal services for small businesses and consumers where AI and automation can have transformative impact.

Paul Philip, Chief Executive of the Solicitors Regulation Authority, said:

"Smart use of technology could help tackle the problem that far too many people struggle to access expert legal advice. It will help us further build on our work to encourage new ways of delivering legal services, benefiting both the public and small business."

In the Maritime and Coastguard Agency, the Regulators' Pioneer Fund investment will create the Maritime Autonomy Regulation Lab (MAR Lab) to bring together industry specialists, academics and government to pioneer new regulatory approaches and make data available to the emerging smart shipping industry.

The project will inform UK legislation for a domestic framework for autonomous vessels to attract international business and support and promote testing in the UK's territorial waters. It will also support government efforts to establish a new proactive and adaptive international regulatory framework for autonomous vessels at the International Maritime Organisation.

We have established a Regulators' Innovation Network to help foster a culture of experimentation across regulators and share best practice. The network is driving greater integration with the catapults, incubators and accelerators that support start-ups and established businesses to develop new ideas.

We will ask regulators to go further to evaluate the impact of their initiatives on innovation. The majority of regulators have an economic growth duty, requiring them to have regard to the desirability of promoting economic growth alongside the delivery of protections set out in legislation. We will consider whether to commence statutory reporting requirements for regulators on the impact of the economic growth duty, with a view to driving greater self-evaluation.

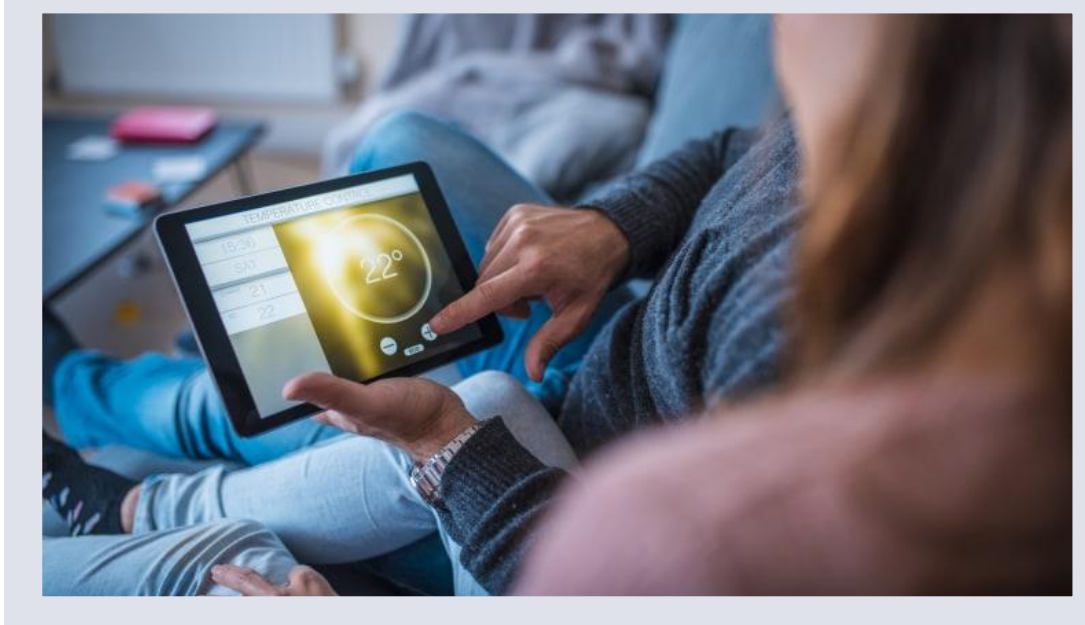
Promoting entry into the energy sector

Ofgem's Innovation Link supports businesses looking to launch new products, services or business models by providing fast, frank feedback, enabling businesses and investors to operate with confidence. It also offers a regulatory sandbox to allow innovators to trial new products, services and business models in a real-world environment for a fixed period without some of the usual rules applying.

The regulator has backed novel propositions such as peer-to-peer local energy trading platforms, which allow residents in urban areas to source their energy from local renewables and trade that energy with their neighbours – driving forward the government's Clean Growth Grand Challenge. Colin Calder, chief executive of PassivSystems, said:

"We now have the go ahead to break the traditional rules of the energy market in order to build a platform for peer-to-peer trading. This project aligns with our vision to drive reform in energy markets and is a perfect fit with our expertise in blockchain technology."

Through the Regulators' Pioneer Fund, Ofgem is taking its efforts to stimulate entry into the sector to a new level. It is working with the Energy Systems Catapult to create a Future Services Lab to trial potential changes to the retail energy market. Households will be invited to participate in small trials of alternative retail models. A cross-functional team of policy experts, service designers and researchers will constantly visit and gather feedback from these trials, rapidly iterating future plans to find the best model to roll out.



The utility regulators Ofwat, Ofgem and Ofcom are exempt from the economic growth duty. In October, HM Treasury and the Department for Business, Energy and Industrial Strategy jointly consulted on how these regulators could drive greater innovation in the sectors they regulate, including whether there was a case for introducing an innovation duty. The consultation closed in January and we will announce how we will take forward its findings later this year.

Our Smart Data Review considered how we can accelerate the development and use of new data-driven technologies and services to improve consumer outcomes. Initiatives such as Open Banking have shown how putting consumers in control of their data can enable the development of innovative services. We will extend this transformation to other markets such as energy and pensions.

The opportunities from sharing data are not restricted to these markets. For example, the Regulators' Pioneer Fund is investing in a Solicitors Regulation Authority-led project to back data-driven entry into the underdeveloped legal services market for small businesses and consumers, while the Future of Mobility Regulatory Review is considering how to boost sharing of transport data. **We will survey innovators and regulators to identify data that could be shared to enable disruptors to enter markets and deliver better outcomes for all.** We will bring forward a National Data Strategy to unlock the power of data in the UK economy and government, while building public confidence in its use, and will consult on the strategy in autumn 2019.

Data-driven innovation can facilitate new forms of competition and disruption in markets. Platforms hold large volumes of data and that is an asset, which allows for data driven innovation. But the Expert Panel on Competition in Digital Markets has found that there are barriers to competition, giving large companies an advantage, and that we should consider data openness. We are considering the Panel's findings and will set out our approach later this year.

Improving access

We will support innovators to navigate the regulatory landscape and receive timely, joined-up feedback on novel propositions.

The case for change

Clear and timely regulatory advice is vital for innovators who are developing new products, services and business models. Where businesses face lengthy, costly, complex or uncertain processes to secure regulatory approvals, they are less likely to be able to persuade potential investors or consumers of the merits of their innovation – and less likely to innovate.

The Fourth Industrial Revolution is characterised by technologies whose applications are vast and which straddle multiple sectors, jurisdictions and institutions. Innovative businesses often find themselves joining up a complex web of regulatory interests that are organised along traditional sectoral lines. 69% of businesses from a range of sectors believe that regulators do not work closely enough with each other²⁵.

Innovative businesses are twice as likely as others to seek regulatory information and advice²⁶. Where businesses struggle to secure advice from regulators, external business agents fill the gap. The average business spends £8,400 per year on such agents²⁷. In some cases, third parties over-interpret regulatory requirements and deter innovation – with the effect that business investment is diverted into compliance activity rather than R&D. Innovations which provide greater consumer choice or deliver social or environmental benefits are lost.

Action is needed to simplify the path for innovators to bring new products and services to market. As well as supporting domestic innovation, advisory services can attract internationally mobile businesses seeking to establish in the UK.

Supporting the revolution in life sciences

New discoveries and the application of new technologies mean we can diagnose illnesses earlier and more accurately, create new treatments and ensure existing ones are more effective.

The UK is extraordinarily well placed to play a leading role in this revolution in the life sciences, with strengths in innovation, research, healthcare and business. To support these innovations to come to market, the Medicines and Healthcare Products Regulatory Agency's (MHRA) Innovation Office provides a single point of access to regulatory advice on the development of innovative medicines, medical devices or manufacturing processes. The service has grown in popularity since its inception in 2013, receiving 190 enquiries in 2018.

The service helps to make regulatory information clear and accessible to those who are working on innovative research, supporting a key goal in the second Life Sciences Sector

²⁵ PA Consulting (2018).

²⁶ BEIS (2018a)

²⁷ BEIS (2018a).

Deal to ensure the UK remains one of the best places in the world to develop life sciences projects, to protect health and improve lives.

The service has helped secure significant investments into the UK life sciences industry. John Parker, Director at AstraZeneca said:

“We genuinely believe that having easy access to MHRA in this manner provides a real competitive advantage to UK based companies”

In the Life Sciences Sector Deal, the MHRA committed to engage with industry to understand how it can further develop its offer by the end of 2019.

Our plan

Entrepreneurs and innovative firms should be able to find their way through the UK’s regulatory landscape with ease and receive timely, joined-up feedback on novel propositions.

We will consult on a digital Regulation Navigator for businesses to help them find their way through the regulatory landscape and engage with the right regulators at the right time on their proposals. We will ensure that this is integrated with action to enhance the government’s digital offer to business in areas such as tax, grants, trade and investment, and build awareness of the available offer.

Initiatives such as the Financial Conduct Authority’s regulatory sandbox (p.19) have helped reduce the time and cost of bringing new products and services to market and enabled businesses to win contracts and secure access to finance. **We are funding greater investment in specialist regulatory advice services for innovators** through our Regulators’ Pioneer Fund, to ensure that innovators who are developing novel proposals with potential for wider economic, societal or environmental benefit are supported to do so.

Simplifying interactions with local authorities

Primary Authority enables businesses to form a legal partnership with one local authority, which then provides assured and tailored advice on a range of regulations and standards. It is particularly beneficial to businesses that operate across a number of local authority areas, as other local regulators must respect the guidance that the business has received from the Primary Authority.

A business can either enter a direct partnership, so it receives advice tailored to its specific needs, or alternatively it can join a trade association to benefit from a co-ordinated primary authority.

The number of UK businesses with Primary Authority partnerships has grown to 73,580 as the benefits of tailored regulatory advice are more widely recognised. Local authorities also appreciate the greater clarity over where responsibility lies and the opportunity to build stronger relationships with business. There are now 188 local authorities acting as a Primary Authority.

Innovative businesses often find themselves joining up multiple regulators to win approval for their propositions, adding cost and delays. The Fourth Industrial Revolution will see more

complex innovations emerging that straddle different regulatory regimes. **We will scope and consult on measures to enhance co-ordination between regulators to ensure that innovations are guided smoothly through the system.** For example, we have established a virtual Shale Environmental Regulator Group to act as a single-entry point for the environmental regulation of the shale gas industry, bringing together the Environment Agency, the Health and Safety Executive and the Oil and Gas Authority.

In some cases novel products, services and business models can face undue regulatory hurdles, despite being in line with regulatory goals. We want to hear where rules or processes are inappropriately constraining innovation, so that regulators can review, clarify and potentially amend their approach. **We will review whether the Regulation Navigator can provide this function, or whether other action is required.**

To promote greater focus on performance, **we will invite regulators to develop metrics on the service that they provide to innovators. We will ensure that data from specialist advice services is fed into the Regulatory Horizons Council,** so that it can advise on where regulatory change or additional investment may be needed to enable innovation to thrive.

Building dialogue

We will build dialogue with society and industry on how technological innovation should be regulated and give innovators confidence in our approach.

The case for change

Innovation creates change and uncertainty. This always carries a degree of risk, with the potential for harm as well as benefit. Our regulatory system is intended to manage this risk at a level which is acceptable to the public.

The UK has strengths in policy consultation. Unlike many other administrations we engage on our policy intent, taking stakeholder views into account before laws are drafted, and set out clearly how we have reflected stakeholder views in our law-making. Businesses and citizens value the UK's transparent and predictable regulatory process.

In some domains, people feel that decisions about how technology is used are beyond their influence. Where technologies with far-reaching implications emerge, we need to conduct earlier engagement with the public, experts and industry to understand their views on how technological applications should be regulated.

We need to develop a more sophisticated model of engagement where ethical and moral issues arise and ensure that issues such as risk and uncertainty are discussed appropriately. We need to build trust and enable both consumers to have confidence in innovations and businesses to have confidence in our stable and proportionate regulatory system.

Leading the public dialogue on mitochondrial replacement treatment

Mitochondria are present in almost all human cells and generate the majority of their energy supply. Unhealthy mitochondria can cause genetic disorders known as mitochondrial disease, which can have devastating effects on the families that carry them. For many patients with mitochondrial diseases, preventing the transmission of the disease to their children is a key concern.

In 2012, the Human Fertilisation and Embryology Authority undertook a sustained engagement programme to determine public acceptability of the use of mitochondrial replacement treatment, characterised in the media as 'three parent babies'. The programme included a breadth of engagement tools, including workshops, a public survey, open meetings and focus groups. It invited trusted scientific figures to take part in the debate.

The regulator found that despite certain ethical concerns there was general support for permitting mitochondria replacement in the UK, so long as it is safe enough to offer in a treatment setting and is done so within a regulatory framework. Following legislation, in 2017 the UK became the first country in the world to license mitochondrial donation techniques to allow women who carry the risk of serious mitochondrial disease to avoid passing it onto their children.

Our plan

We want innovators and the public to have confidence in the UK's regulatory regime. We will build dialogue with society and industry on how technological innovation should be regulated.

We will ask the Regulatory Horizons Council to identify priorities for greater public engagement on regulation of innovation. For example, where technologies pose complex ethical or moral considerations greater public engagement may be appropriate to shape government thinking on appropriate regulatory frameworks. Government departments and regulators will continue to lead public engagement on their policies, working with expert bodies such as the Centre for Data Ethics and Innovation.

As part of its role, **the Better Regulation Executive will provide support, advice and share best practice with policymakers and regulators on public engagement techniques to support appropriate regulation of technological innovation**, working with partners such as Sciencewise. The Better Regulation Executive will build capability in novel and creative public engagement techniques that go beyond public consultation in this important area.

Engaging the public on regulation of drones

Drone technology is advancing rapidly with the potential to perform critical services in everyday life – from transporting urgent medical supplies to bridge inspection and repair. UK cities and regions need to consider what they want the future of drone applications to look like. PwC estimates that by 2030 drone use could increase UK GDP by £42 billion²⁸.

With support from the government's Industrial Strategy Challenge Fund, the innovation foundation Nesta funded public use analysis of drones in five cities for activities from inspecting burning buildings to traffic incident response. It worked with the government and the Civil Aviation Authority and convened local stakeholders to assess demand and identified the technical, economic and regulatory success factors for safe drone deployment at scale in cities.

The programme has concluded that there is demand for drones, which can fulfil socially beneficial goals. However, there are regulatory challenges that need to be solved – from how to deploy drones over long distances to what is publicly acceptable in terms of noise, privacy, safety and other issues. These issues are being considered as part of the Department for Transport's Aviation Strategy 2050 green paper, looking at how a flexible regulatory framework can be established to support transport innovation under the Future of Mobility Grand Challenge and beyond.

Regulators play an important role in shaping the public dialogue on how technological innovation should be governed. **We will encourage regulators to build public dialogue into experimentation initiatives** (such as those financed through the Regulators' Pioneer Fund), so that public views are considered as new products, services and business models are trialled.

²⁸ PwC (2018)

Leading the world

We will work with partners across the globe to reduce regulatory barriers to trade in innovative products and services.

The case for change

In today's global marketplace, innovators developing products and services in the UK want to be able to sell them across the world. Where regulatory approaches differ between administrations this can add burden to UK exporters and impact upon importers bringing goods and services to the UK, leading to higher prices for consumers.

The UK is recognised across the world for its regulatory environment which protects citizens and is open to innovation. Our performance is scored top of all the countries in the OECD's 2018 Regulatory Policy Outlook and our regulatory frameworks have been emulated across the globe. As we leave the European Union and forge a new path for ourselves, we will continue to play an important role in shaping how regulation is developed internationally.

We will collaborate with like-minded international partners to reduce regulatory barriers to trade, through mechanisms such as the adoption of international standards, mutual recognition agreements and free trade agreements. We will encourage our regulators to play an active role in shaping international thinking on how innovation should be regulated.

We will also continue to provide global leadership on standards, building on the British Standards Institution's strong track record in the international recognition and global adoption of UK standards.

Forging a global partnership on regulation of financial innovation

The financial system is inherently transnational. As we take an innovation-enabling approach to financial technologies, it is important that we move in step with the rest of the world.

The Financial Conduct Authority is spearheading international collaboration through a new Global Financial Innovation Network, established in January. The network includes 29 organisations – from the Australian Securities & Investments Commission to the Monetary Authority of Singapore – who are committed to supporting financial innovation in the interests of consumers.

The network is piloting an environment that will allow firms to simultaneously trial and scale new technologies in multiple jurisdictions, gaining real-time insight into how a product or service might operate in the market. It also enables regulators to collaborate and share experience of innovation in respective markets, including emerging technologies and business models.

Our plan

We will work with partners across the globe to reduce regulatory barriers to trade in innovative products and services.

We have established a partnership with the World Economic Forum Centre for the Fourth Industrial Revolution in San Francisco to develop regulatory approaches for new technologies. The partnership work will focus on areas of innovation which align with the UK's Industrial Strategy Grand Challenges, such as:

- AI and machine learning;
- autonomous and urban mobility;
- drones and tomorrow's airspace; and
- precision medicine

Our collaboration with the World Economic Forum will showcase the regulatory sandboxes, testbeds and labs we have developed in the UK and promote their adoption across the globe.

Shaping international norms on regulation of the digital economy

Many digital technologies are inherently cross-border, with firms able to switch between different jurisdictions at low cost while retaining a global customer base. Co-ordination between administrations and successful co-operation is needed in order to ensure the effectiveness of regulation and to protect the public.

The Department for Business, Energy and Industrial Strategy is working with the Organisation for Economic Co-operation and Development (OECD) to explore the cross-border regulatory challenges of the emerging digital economy. The project will provide guidance to policy makers and regulators to respond to those challenges.

The work will deepen the knowledge and understanding of how key better regulation practices and tools can foster the development and uptake of beneficial digital innovation. It will identify strengths and weaknesses of existing regulatory policy approaches to addressing the regulatory challenges posed by digital innovations, with a view to highlighting opportunities and possible areas for improvement.

We have also invited the Organisation for Economic Co-operation and Development to review the UK's working practices in relation to international regulatory co-operation. **We will improve awareness of the effects of regulation on trade among government departments and regulators** so that impacts are systematically considered.

We will seek to include ambitious chapters on good regulatory practices and regulatory co-operation in future free trade agreements that the UK negotiates following our exit from the European Union. Where we work with other countries to share good regulatory practice, we will set out the importance of ensuring that regulation and standards facilitate innovation.

Standards open up new markets, connect companies to international supply chains and are a passport to trade. As a global leader in standards, guidance and good practice, **we will work with international partners and multilateral fora to develop and promote standards for**

new and emerging technologies, capturing knowledge from publicly-funded R&D pilots, testbeds and technology adoption programmes.

We will continue working alongside other nations in the international and regional standards organisations, to help secure globally accepted standards for innovators to collaborate effectively in international markets. We are funding the first Commonwealth Standards Network, delivered by the British Standards Institution, to promote awareness and use of international standards and boost trade across the Commonwealth.

Setting global standards on smart cities



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

Conclusion

This White Paper is our long-term strategy for maintaining our world-leading regulatory environment as we enter the Fourth Industrial Revolution. The Ministerial Working Group on Future Regulation will drive its delivery, supported by the Better Regulation Executive.

The White Paper is a plan for the whole of government, shaping how we will regulate in areas from healthcare to transport. We want to give businesses confidence to innovate and invest in the UK and give citizens confidence in our protections.

In addressing these issues we respect the devolution settlements with Scotland, Wales and Northern Ireland. We will work with our partners in the devolved administrations and local authorities to share our innovation-enabling approach and ensure that every part of the UK benefits from the Fourth Industrial Revolution.

Summary of commitments

Facing the future

- We will **establish a Regulatory Horizons Council to identify the implications of technological innovation** and advise the government on regulatory reform needed to support its rapid and safe introduction.
- The Council will **prepare a regular report on innovation across the economy, with recommendations on priorities for regulatory reform** to put the UK at the forefront of the industries of the future.
- The **Ministerial Working Group on Future Regulation, chaired by the Business Secretary, will oversee the government response to the Council's recommendations.**

Focusing on outcomes

- We will **pilot an innovation test so that the impact of legislation on innovation is considered** during the development of policy, introduction and implementation of legislation and its evaluation and review.
- During the pilot, we will **invite the Regulatory Policy Committee to scrutinise the application of the innovation test**, to ensure that innovators have confidence in how government is developing new legislation.
- We will **promote new ways to trigger when post-implementation reviews of legislation are undertaken** to ensure that legislation does not inadvertently 'lock in' outdated technologies or approaches.
- We will **develop tools for regulators to support them to review their guidance, codes of practice and other regulatory mechanisms** to ensure that they provide flexibility for those businesses that want to innovate, while ensuring a clear route to compliance.

- We will **support business, policymakers and regulators to make effective use of standards where appropriate** as a complement to legislation.
- We will **invite the Office for Product Safety and Standards, British Standards Institution, National Physical Laboratory and UK Accreditation Service to set out their vision for how the development and review of standards should evolve** as we enter the Fourth Industrial Revolution.

Supporting experimentation

- We will **examine the case for expanding the Regulators' Pioneer Fund in future to help regulators to keep pace with technological innovation** and enable the emergence of new products, services and business models.
- We will **examine the case for extending the Regulators' Pioneer Fund to local authorities in future**, in order to help them support greater testing and trialling of innovations in their area.
- We have **established a Regulators' Innovation Network to help foster a culture of experimentation across regulators** and share best practice.
- We will **ask regulators to go further to evaluate the impact of their initiatives on innovation** and consider whether to commence statutory reporting requirements for regulators on the impact of the economic growth duty.
- We will **survey innovators and regulators to identify data that could be shared to enable disruptors to enter markets** and deliver better outcomes for all.

Improving access

- We will **consult on a digital Regulation Navigator for businesses to help them find their way through the regulatory landscape** and engage with the right regulators at the right time on their proposals.
- We have **financed greater investment in specialist regulatory advice services for innovators through the Regulators' Pioneer Fund**.
- We will **scope and consult on measures to enhance co-ordination between regulators to ensure that innovations are guided smoothly through the system**.
- We will **consider whether the Regulation Navigator should include functions for businesses to raise where rules or processes are inappropriately constraining innovation**, so that regulators can review, clarify and potentially amend their approach.
- We will **invite regulators to develop metrics on the service that they provide to innovators**.
- We will **ensure that data from specialist advice services is fed into the Regulatory Horizons Council**, so that it can advise on where regulatory change or additional investment may be needed to enable innovation to thrive.

Building dialogue

- We will **ask the Regulatory Horizons Council to identify priorities for greater public engagement on regulation of innovation**.

- We will **provide support, advice and share best practice with policymakers and regulators on public engagement techniques** to support appropriate regulation of technological innovation.
- We will **encourage regulators to build public dialogue into experimentation initiatives** (such as those financed through the Regulators' Pioneer Fund), so that public views are considered as new products, services and business models are trialled.

Leading the world

- We have **established a partnership with the World Economic Forum Centre for the Fourth Industrial Revolution in San Francisco** to develop regulatory approaches for new technologies.
- We are **working with the Organisation for Economic Co-operation and Development (OECD) to explore the regulatory challenges of the emerging digital economy.**
- We will **improve awareness of the effects of regulation on trade among government departments and regulators** so that the impacts of regulatory divergence are systematically considered.
- We will **seek to include ambitious chapters on good regulatory practices and regulatory co-operation in future free trade agreements** that the UK negotiates following our exit from the European Union.
- We will **continue working alongside other nations in the international and regional standards organisations, to help secure globally accepted standards** for innovators to collaborate effectively in international markets.

Glossary

Accelerator: Fixed-term, selective programmes for start-up businesses to accelerate their growth, typically including investment, networking and mentoring.

Catapult: Physical centres supporting collaborative late-stage research and development, typically including access to technical capabilities and equipment. See: www.catapult.org.uk.

Incubator: Shared working space for start-up firms to incubate their business models, typically facilitating access to finance, networking and mentoring.

Sandbox: Fixed-term trial of innovative product, service or business model in a live market environment under enhanced regulatory supervision.

Testbed: Platform for conducting trials of new technologies.

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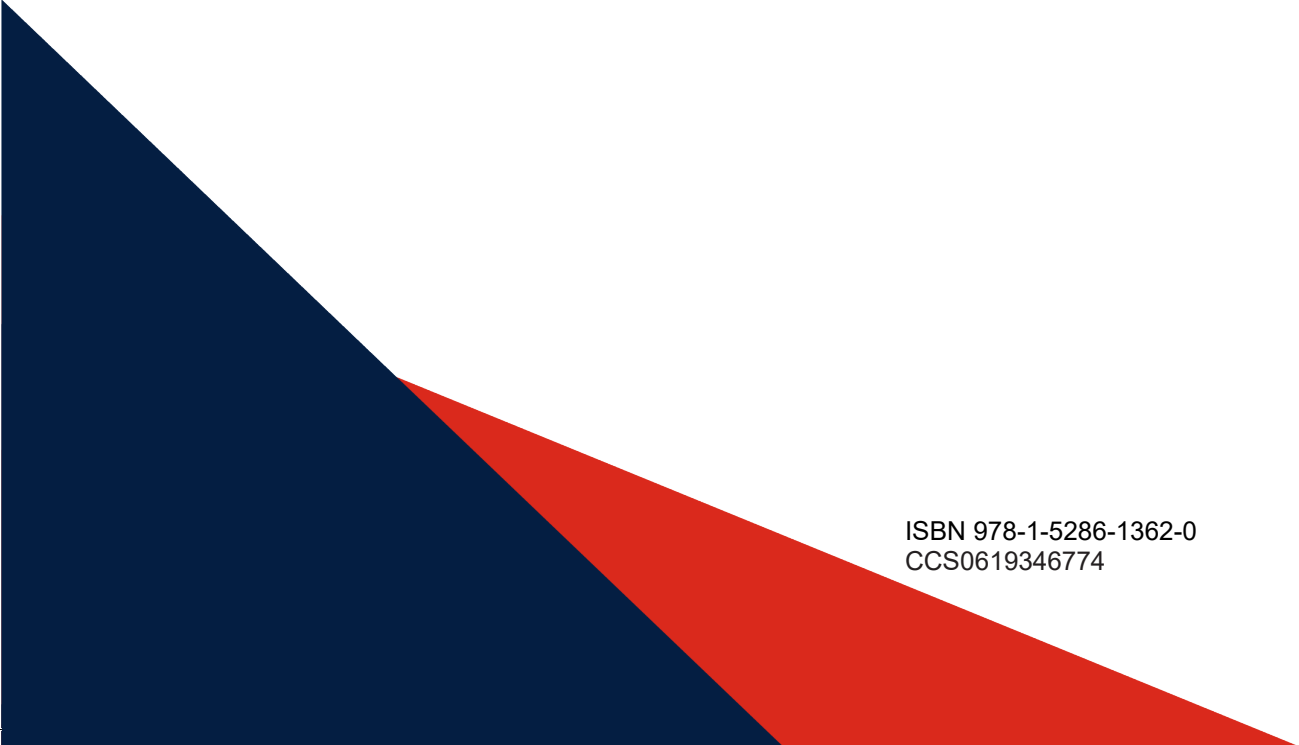
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ISBN 978-1-5286-1362-0
CCS0619346774