

Agile Regulation for the Fourth Industrial Revolution A Toolkit for Regulators

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Preface

From autonomous vehicles to biotechnologies, technological breakthroughs across the digital, biological and physical spheres are heralding a Fourth Industrial Revolution. Governed well, these innovations can help power economic growth and address the world's most pressing social and environmental challenges.

But regulation can struggle to keep pace with innovation, hindering the introduction of new ideas, products and business models, while leaving citizens with outdated protections. A more agile, flexible approach to regulation is needed in order to seize the potential of the Fourth Industrial Revolution to change lives for the better.

The COVID-19 pandemic has reinforced the need for speed. Across the globe, governments have been forced to fast-track changes to regulation to enable innovations from telemedicine to drone delivery to help their economies adapt to disruption. The “regulate-and-forget” era has passed: to grasp the opportunities and mitigate the risks from innovation and disruption, governments need to adopt an “adapt-and-learn” approach instead.

This guide provides regulators with a range of techniques they can employ to help respond in a more agile way to innovation and disruption. It builds on the World Economic Forum's 2018 White Paper, *Agile Governance: Reimagining Policy-making in the Fourth Industrial Revolution*,¹ which called for a faster, more agile approach to governing emerging technologies and the business models and social interaction structures they enable.

The guide outlines seven approaches to regulation in the Fourth Industrial Revolution, building on the foundations of good regulatory practice (Chapter 1). Drawing on the latest evidence and practice from around the world, the guide sets out techniques that regulators are employing to:

- Help identify the implications of emerging technologies (Chapter 2)
- Set clear outcomes for business in how they are used (Chapter 3)
- Create space to experiment in how these outcomes are achieved (Chapter 4)
- Use technology to monitor outcomes and intervene when needed (Chapter 5)
- Harness industry-led governance of innovation (Chapter 6)
- Promote regulatory coherence across the whole of government (Chapter 7)
- Collaborate across international borders to ensure that rules are interoperable and risks can be tackled jointly (Chapter 8).

The guide demystifies what regulatory sandboxes, challenges and one-stop shops really are and explores the trade-offs between different regulatory strategies. It includes tips from leading regulators on how to apply these techniques in practice, and concludes with ideas on how to mainstream these approaches across the whole of government (Chapter 9).

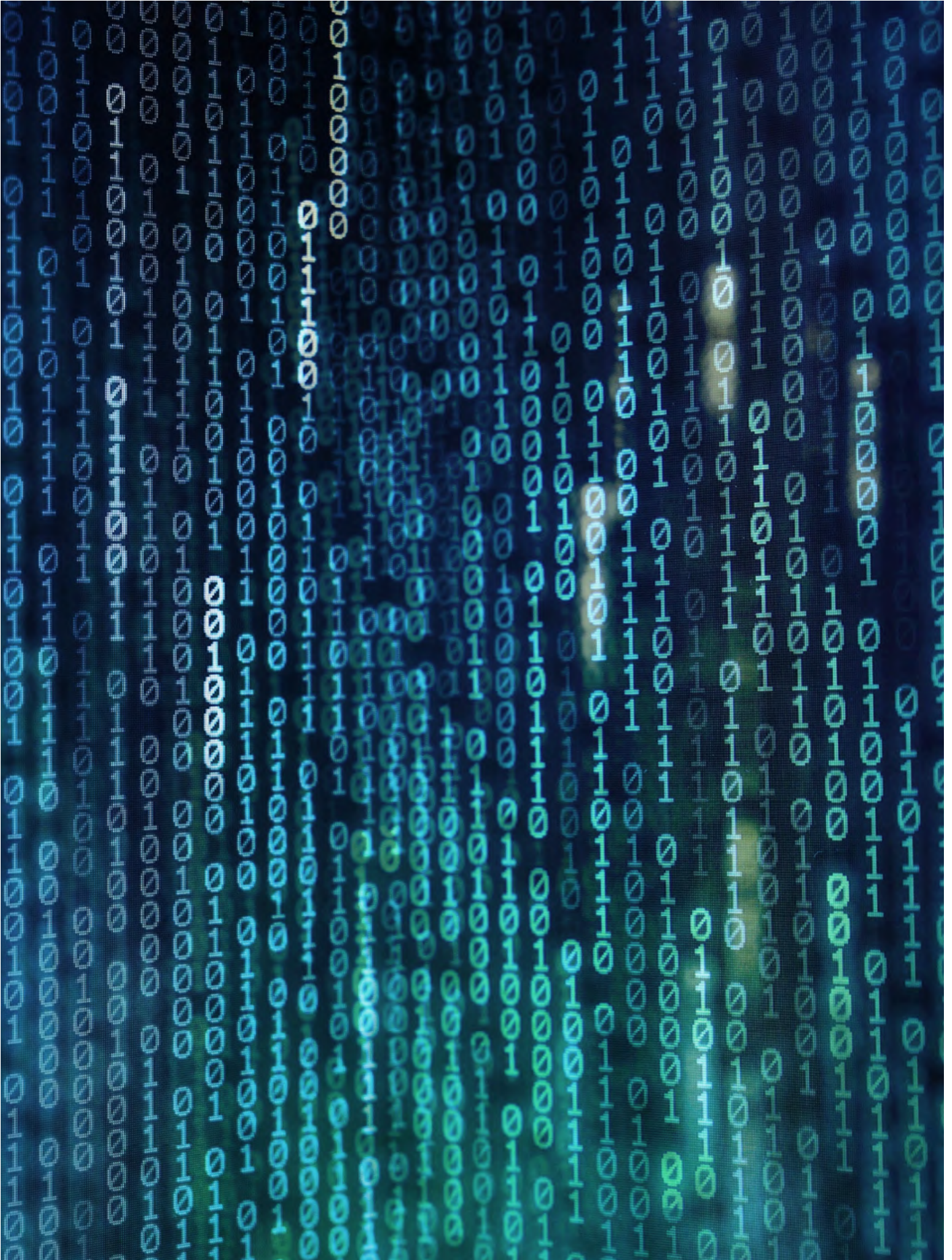


Photo: Suebsiri/Getty Images

The Fourth Industrial Revolution offers the potential to change lives around the world for the better. But to realize this potential, a new approach to governance is needed.

1.1 The Fourth Industrial Revolution

The Fourth Industrial Revolution sits apart from previous industrial revolutions. Whereas steam power, electricity and information technology created the first three industrial revolutions, the Fourth Industrial Revolution is characterized by parallel technological breakthroughs within and across the digital, biological and physical spheres.

The list of emerging technologies can seem endless, including artificial intelligence (AI), gene editing, the internet of things, autonomous vehicles, 3D printing, nanotechnology, advanced materials, energy storage, drones, quantum computing – to

name just a few. The resulting industrial revolution is unprecedented in its speed, depth and breadth, offering both promise and peril as it changes nearly every industry in every country.

The COVID-19 pandemic has accelerated this transition in some areas – driving the adoption of digitally-enabled ways of producing goods or providing services in a world where physical interaction becomes less possible. It has also exposed the flaws of regulatory systems that have not kept pace with innovation, hindering the adoption of new ways of doing things without providing public protections.

1.2 Regulation and the Fourth Industrial Revolution

The pace, scope and complexity of the Fourth Industrial Revolution presents novel challenges for governance – and especially law and regulation:

- Regulation can struggle to keep pace with the rate at which new ideas, products and business models emerge (the “pacing problem”).
- Regulators can struggle to respond to innovations whose implications lie partly outside their sectoral or geographical jurisdiction,

requiring coordination with others (the “coordination problem”).

- Regulators can struggle to assign responsibility for managing risks to different actors in dynamic and complex environments (the “responsibility problem”).

A more agile approach to regulation is needed in order to unlock the potential of the Fourth Industrial Revolution and shape it in a way that protects citizens and reflects their values.

What is regulation?

In this guide, the term “regulation” refers to the mechanisms by which governments set requirements on businesses, and the term “regulator” refers to a person or authority who develops or administers regulation. As defined by the Organisation for Economic Co-operation and Development (OECD), regulation includes all laws, formal and informal orders, subordinate rules, administrative formalities and rules issued by non-governmental or self-regulatory bodies to whom governments have delegated regulatory powers.²

Governments regulate business to deliver better outcomes for the economy, society and the environment – for example to safeguard citizens’ privacy, protect wildlife from pollution or uphold fair competition among businesses. While governments may also regulate the actions of individuals, public-sector or civil society organizations, the focus in this guide is on the regulation of business in the Fourth Industrial Revolution.

1.3 The foundations of good regulatory practice

Regulation introduces both benefits and costs. It can stimulate ideas and can block their implementation.³ It can increase or reduce the risk of investing in new products and business models, and determine how much funding is available for innovation and how much goes into tick-box compliance.⁴ It can influence consumer confidence and demand, and determine whether firms enter or exit a market.⁵

For this reason, most developed economies have policies, procedures and institutions to govern how regulations are developed, administered and reviewed. While approaches vary, such policies typically affirm the importance of openness, proportionality and fairness. These foundational concepts are important for all regulation and are covered extensively in other resources. They are only treated briefly here, referring readers to comprehensive guidance from the OECD⁶ and others.



Openness

A core principle of regulatory policy is that governments should support transparency and participation in the regulatory process to ensure that regulation serves the public interest and is informed by those that it affects or who hold an interest in it. In the fast-moving, far-reaching context of the Fourth Industrial Revolution, it is vital that regulators engage citizens and stakeholders in a way that upholds accountability and earns trust.⁷

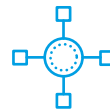
Open regulators seek to:

- Create informed public understanding of the issues they are trying to tackle, explaining what can and cannot be achieved
- Engage citizens and stakeholders at key points to shape policy goals, develop policy options, design regulatory interventions, support successful implementation and review the impact of interventions
- Give all citizens and stakeholders equal opportunities to provide their views, in a way that ensures adequate time and imposes minimal burden
- Reach out to citizens and stakeholders whose views may be underrepresented (e.g. start-ups, small businesses) and acknowledge the interest of those whose voices cannot be heard, including future citizens
- Engage respectfully and show how citizen and stakeholder views have been considered and

have shaped decision-making, and explain why some have not been adopted

- Explain the impact of their actions on the issues that citizens and stakeholders want them to tackle, and set out where further action may be needed.

Stakeholder engagement should not be viewed as a box to tick but as a process through which regulators can gather continuous learning about how to design and administer better regulation. As regulation becomes more agile, it is important for regulators to find more flexible ways to support understanding, participation and oversight by citizens and stakeholders.



Proportionality

An equally vital principle is for regulation to be proportionate in the costs that it incurs in pursuit of desired benefits. The rapid pace of the Fourth Industrial Revolution should not be an excuse for poorly designed or implemented interventions that introduce unnecessary burden. Regulatory policy tools, such as regulatory impact assessments⁸ and post-implementation reviews, support regulators in designing and administering more proportionate interventions.

Proportionate regulators seek to:

- Clearly identify policy goals and consider a range of options for how these goals can be achieved, including means other than regulation
- Assess the direct and indirect benefits and costs of proposed interventions on the economy, society and the environment, including distributional effects
- Engage stakeholders to test their assumptions, invite scrutiny of the benefits and costs of proposed regulations and revise their approach accordingly
- Design, administer and enforce regulation in a way that focuses on the risk posed and minimizes unnecessary costs and side effects
- Pilot regulatory interventions where possible to understand their true benefits and costs and optimize them before wider roll-out
- Monitor and evaluate the impact of regulations in a timely and proportionate way, to ensure that they remain up to date, efficient and effective, and lead reform as appropriate where they do not.

As with stakeholder engagement, it is crucial that the assessment and review of the impact of regulation are not viewed as hoops to jump through, separate to the process of developing and administering regulation. A positive trend in the Fourth Industrial Revolution is the increased use of piloting as a means for regulators to learn about the effectiveness and efficiency of interventions and adapt them accordingly.



Fairness

Fairness is an essential foundation of the law. Regulatory decisions should be made on an objective, impartial and consistent basis, without conflict of interest, bias or improper influence. This enables businesses to compete on a level playing field, and helps ensure that the best ideas, products and business models emerging through the Fourth Industrial Revolution are those that succeed.

Fair regulators seek to:

- Give all businesses equal opportunities to provide their views, recognizing that small businesses and start-ups may be less well represented than larger or incumbent businesses

- Ensure that all businesses have access to the same information about current or future regulatory requirements, at the same time
- Ensure that all businesses with the same characteristics are subject to the same regulatory requirements and have access to the same regulatory support
- Ensure that all businesses that pose the same risk of non-compliance with regulation face the same risk of inspections and enforcement, without bias
- Apply sanctions consistently to businesses with the same characteristics that do not comply with regulation
- Ensure that businesses have mechanisms to appeal unfair regulatory decisions or raise complaints.

As with openness and proportionality, it is possible that fairness can be overlooked in the rush to respond to the opportunities and risks of the Fourth Industrial Revolution. Aside from the risk of legal challenge, regulatory approaches that inappropriately favour certain businesses are likely to distort markets and lead to worse public policy outcomes. Vigilance is needed to ensure that fairness is upheld in regulatory processes.

1.4 Moving beyond the foundations

These foundational concepts of regulatory practice are necessary but not sufficient to manage the pacing, coordination and liability problems that the Fourth Industrial Revolution introduces. The rest of this guide explores the novel regulatory practices that a growing number of governments are employing to help manage the opportunities and risks of technological change.

This approach may be termed “agile regulation”, building on the concept of agile technology development. As employed in the private sector, agile technology development values focusing on outcomes over rules, responding to change over following a plan, encouraging wider participation over control and fostering self-organization over centralized governance. Agile regulation forms part of the family of agile governance techniques introduced in the 2018 White Paper.

Agile regulators focus on the future and set clear outcomes for business, giving them space to experiment in how these are achieved (Chapters 2, 3 and 4). They recognize the role of industry and others in the governance of innovation and harness technology to monitor outcomes and

intervene when needed (Chapters 5 and 6). They collaborate across institutional, regional and international boundaries to ensure that rules are interoperable and risks can be tackled jointly (Chapters 7 and 8).

This guide provides examples of how governments are applying these concepts in practice, to help inspire and support regulators navigating similar challenges. It is not a good-practice guide – in many cases, there is too little evidence of the impact of these initiatives to definitively recommend them – but a first step in bringing together this field of regulatory practice. It will be followed in 2021 by further work by the OECD on principles for effective rule-making in the Fourth Industrial Revolution.

Throughout this guide, the links between these practices and with the foundations of good regulatory practice are explained. While the techniques in this document can be employed independently, they can be mutually reinforcing, and regulators are encouraged to consider them in conjunction. Chapter 9 provides brief conclusions and examples of how an agile regulatory approach may be mainstreamed in general across government.

② | Anticipatory regulation



Photo: Suebsiri/Getty Images

The rapid pace of technological change means that regulators need to become more adept at identifying innovations and the opportunities and risks they present.

Without foresight, regulators are vulnerable to ill-timed or disproportionate interventions that may fail to maximize the potential of new ideas, products and business models or mitigate risks to citizens and the environment. The impact on businesses can be significant – in one UK study,

92% of the businesses surveyed thought they would lose revenue if regulators failed to keep pace with disruptive change in the coming two to three years.⁹

This chapter examines how regulators can take a more anticipatory approach. While it is not possible to accurately predict the future, the use of foresight can help regulators develop or adapt their interventions in a more open, timely and proportionate way that is more resilient to future change.

2.1 Identifying innovations and their implications

Anticipatory regulation involves the identification of changes in the wider world over a given period and consideration of the implications of these changes (jointly or individually) for the regulator's current and future approach. In the context of the Fourth Industrial Revolution, much focus is on the impact of technological innovation.

A growing number of units have been established around the world to advise regulators on the impacts of technological innovation and the resulting need for reform. Examples include Canada's External

Advisory Committee on Regulatory Competitiveness, Sweden's Committee for Technological Innovation and Ethics (see below) and the United Kingdom's Regulatory Horizons Council. The World Economic Forum has published its own guide to governance gaps surrounding emerging technologies.¹⁰

Many different approaches to gathering such intelligence about the future exist. One approach is to scan the horizon for high-impact innovations with significant regulatory implications¹¹ and use this to help target future reforms:

Identification

Desk research is initially used to identify new ideas, products and business models with significant regulatory implications that are expected to emerge over a specified time horizon. For each innovation, the research seeks to identify, at a high level:

- The potential economic value of the innovation, over a given period
- The potential social and environmental value of the innovation, over a given period
- The need for regulatory intervention to unlock these benefits or address potential harms.

The horizon-scanning process may also draw on data from the regulators' advice or testing initiatives, which can provide important intelligence on future innovation (see Chapter 4).

Engagement

Engagement with innovators, academia and civil society is used to help validate the desk research and identify innovations that may be missing. It is important to engage beyond incumbents and other "usual suspects" to ensure that disruptive innovations are not missed. In the same vein, it is important to gather a diversity of views about the opportunities and risks of the innovations that have been identified and the impact that regulation may have.

Prioritization

A set of criteria is used to identify high-impact innovations where regulatory reform is needed to unlock potential benefits or address potential harms. The level of uncertainty in the data means that this is far from an exact science. As with horizon-scanning, stakeholder engagement may be used to help conduct or validate the prioritization approach and the areas of focus that have been identified.

Adaptation

Just because a technology or innovation has been highlighted as a priority does not mean that regulatory intervention is needed. As outlined in Chapter 1, careful consideration should be given to a range of policy options, with regulation used only where necessary and in a way that focuses on the risk posed and minimizes unnecessary costs and side effects. Even where regulation is needed, careful consideration should be given to the timing of interventions, as discussed in the next section.

Scenario planning is a complementary approach that can be taken forward jointly or independently of horizon-scanning. While the above method helps to identify individual innovations and their implications, scenarios can be used to help consider different ways in which innovations may combine and interact with wider economic, social or environmental developments to create different futures.¹²

For example, the UK Government Office for Science identified four scenarios for how technological developments in mobility would interact with various economic, social and environmental changes in the period to 2040.¹³ Such scenarios can be used to help stress-test current policies or proposed alternatives to ensure their resilience in the Fourth Industrial Revolution.

Identifying the implications of technological innovation for Sweden



Like other jurisdictions, the Swedish Government seeks to maximize the potential of the Fourth Industrial Revolution to support sustainable growth and help address social and environmental challenges.

In 2018, it established the Committee for Technological Innovation and Ethics (Komet) with the mission to help the Government identify policy challenges, contribute to reducing uncertainty surrounding existing regulations and accelerate policy development linked to Fourth Industrial Revolution technologies.

The Committee's task is to highlight any conflicting goals, regulatory challenges and barriers to the responsible use of new technologies and propose how to deal with them. The Committee has published fact sheets on new technologies

such as AI, machine learning, 5G, synthetic biology and blockchain, a number of reports including on regulatory barriers, proposals on enabling experimentation and models to promote responsible innovation. The Committee will provide final recommendations to the government by 31 December 2021.



As with many initiatives in this guide, the research on the impact of such horizon-scanning and foresight activities is limited. Expected benefits include the anticipation of economic, social and environmental opportunities and risks arising from emerging innovations, enabling more timely, proportionate and resilient interventions to manage them.

The lack of data on the impact of such initiatives means that it can be hard for regulators to know how much foresight activity to conduct, with the result that it can often be overlooked. However, adopting a purely reactive approach is unlikely to be sustainable in the Fourth Industrial Revolution and some amount of foresight is necessary to seize potential opportunities and manage emerging risks.

2.2 Issues to consider

Anticipatory regulation and the foundations of good regulatory practice

Foresight should not be viewed as a rush to regulate. Rather, the early identification of issues allows for a more informed and open dialogue with citizens and stakeholders on how the opportunities and risks of an innovation should be managed, and the gathering of better evidence with which to appraise the impact of a range of policy options. The result should be a more timely and proportionate response, underpinned by stakeholder engagement.

In particular, regulators need to apply careful judgement to the question of when to intervene. Act

too late, and the regulator may fail to seize economic opportunities or address emerging risks. But intervene too soon, and the regulator may stifle innovation or develop ineffective rules based on an incomplete understanding of the emerging technology.

In this regard, it is helpful to shift away from a “regulate-and-forget” mindset to one in which regulation is viewed as a cycle of continuous learning and adaptation as the technology develops.¹⁴ In this approach, “soft law” mechanisms, such as regulatory guidance, codes of practice and voluntary standards, are used to steer technological development, with regulation codified as the technology reaches full maturity.

Agile governance of self-driving cars in Japan



The continuous evolution of automotive technology promises a future in which people do not drive cars – cars drive people.

Automotive experts describe a path through which cars progress from having no automation to partial automation (where the vehicle has automated functions like acceleration and steering, but the driver must remain engaged and monitor the environment at all times) and on to full automation (where the vehicle is capable of performing all driving functions in all conditions).

To keep pace with technological development, Japan's Ministry of Land, Infrastructure, Transport and Tourism (MLIT) has built an agile regulatory approach. It includes:

- Using a system of exemptions to permit the trialling of autonomous vehicles that do not meet ordinary regulatory requirements
- Co-developing voluntary technical requirements with industry for the trialling of autonomous vehicles
- Adapting technical requirements based on data from trials and with a focus on



international harmonization (under UNECE World Forum for Harmonization of Vehicle Regulations – WP29)

- Finalizing requirements once the technology is sufficiently distributed in the market.

MLIT aims to create an outcome-focused, technology-neutral regulatory framework that is predictable and stable, with market surveillance used to balance the need for pre-market testing. It aims to develop the systems needed to conduct such surveillance in real time and ensure the prompt intervention and adaptation of its rules.

This more agile approach to regulation supports the principles of good regulatory practice, such as proportionality and openness, but can be in tension with some of the tools that are used. In an agile model, a regulatory impact assessment and stakeholder consultation are not just fixed requirements to be conducted at one point in time, but techniques to be used to inform the continuous adaptation of the regulatory approach.

Work is continuing to consider how these regulatory policy tools should adapt to this new context. For example, the European Commission has introduced a guide to help policy-makers consider the impact of legislation on innovation.¹⁵ The OECD is leading work to examine what a regulatory impact assessment, stakeholder consultation and post-implementation review should look like in the Fourth Industrial Revolution.

Anticipatory regulation as part of a more agile approach to regulation

Foresight enables regulators to adopt a more agile approach to regulation based on continuous adaptation and learning.

A combination of [outcome-focused regulation](#) and [industry self-governance](#), matched with insight from [ongoing regulatory experiments](#) and [data-driven monitoring and evaluation](#), may be used to create a governance framework that is capable of continuous improvement in response to intelligence gained through foresight. In turn, this more responsive regulatory system may provide vital intelligence on future innovation and disruption that can be fed into ongoing foresight activity.

Using foresight to shape the future in the United Arab Emirates



The United Arab Emirates Centennial 2071 plan sets out a vision of a diversified knowledge economy, supported by a future-focused government.

The Dubai Future Foundation helps support this vision by providing the foresight needed to enable the United Arab Emirates to seize emerging opportunities and manage potential risks. Its role extends beyond conducting foresight activity to include disseminating research and technological advances; accelerating the design of policies and projects to respond to these advances; and building capability to respond across government.

One of the ways in which the United Arab Emirates helps translate foresight into regulatory change is through its Regulations Lab (RegLab). RegLab works with the Dubai Future Foundation to invite global innovators to trial new ideas, products and



business models in the United Arab Emirates. Where derogations from regulation are needed, RegLab may approve a testing licence for the experiment. Learning is gathered from the testing phase to inform future changes to regulation that all businesses may benefit from.

Foresight also enables regulators to invest in a more coordinated response to emerging opportunities and risks. The implications of many innovations will lie at least partly outside the jurisdiction of any one authority, requiring greater [coordination across](#)

[regulators in different sectors](#), localities or [countries](#). Earlier insight on innovation and disruption can help avoid the development of fragmented governance frameworks that may hinder trade and innovation or the management of shared risks.

3

Outcome-focused regulation



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The dynamic nature of the Fourth Industrial Revolution means that regulators need to focus more on defining desired outcomes and measuring performance against them.

Excessively prescriptive, “command-and-control” regulation can rapidly become obsolete as new ideas, products and business models emerge. At worst, the effect can be to divert business

resources into tick-box compliance without achieving outcomes for citizens and the environment.¹⁶

This chapter examines how regulators can take a more outcome-focused approach by employing or combining such techniques as goals-based regulation, experimentation clauses and regulatory guidance.

3.1 Focusing regulation on the achievement of goals

Goal-based regulation involves a focus on the achievement of “real-world” outcomes for citizens and the environment.¹⁷ Also called outcome-focused, principles-based or performance-based regulation, it defines high-level goals or outcomes that businesses’ actions must achieve using their own judgement. It is distinct from prescriptive rules-based regulation, which defines in advance precisely what actions businesses must or must not do.

Goal-based approaches are inherently technology-neutral. They increase flexibility for business, enabling them to find the most efficient way to comply and reducing costs for consumers. They can encourage innovation since firms have greater freedom to try out new ideas, products and business models.¹⁸ They can also encourage businesses to think more carefully about how best to achieve a regulatory goal, and not mechanically follow rules.

Goal-based regulation can enhance stability and predictability for business, as public policy goals are set for the long term. It is well-suited to the dynamic

and uncertain context of the Fourth Industrial Revolution, where technological developments combined with economic, social and environmental shifts may rapidly make more prescriptive approaches outdated.

Goal-based approaches can also give regulators greater flexibility in how they use their powers to achieve the best outcomes for citizens and the environment. Where challenging outcomes are set, goal-based regulation can actively drive innovation that delivers benefits for citizens and the environment as businesses develop novel approaches to achieve compliance.¹⁹

A growing number of countries explicitly promote the adoption of a goal-based, technology-neutral approach to the regulation of innovation, including Denmark,²⁰ Japan²¹ and the United Kingdom.²² In Australia, the New South Wales Government established a programme to make existing regulation more technology-neutral, using AI to identify opportunities to remove requirements such as the use of paper documents or signatures.²³

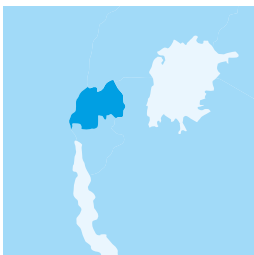
Developing performance-based regulations for drones in Rwanda

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

To unlock the potential of drone technologies, the Rwanda Civil Aviation Authority (RCAA) collaborated with the World Economic Forum to introduce a performance-based regulatory approach. Rather than set prescriptive rules, the RCAA determined acceptable thresholds of risk and required manufacturers and operators to demonstrate how they will meet these performance standards.

The regulatory framework enables any type of drone operation in any location while maintaining

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



The process by which regulation is designed and introduced is covered extensively elsewhere, so this chapter does not provide a step-by-step guide to introducing goal-based regulation or other techniques. Instead, the focus is on the challenges of implementing a goal-based regulatory approach.

Two core challenges of a goal-based regulatory approach are defined in this section:

- Businesses may lack the capacity, capability and, in some cases, motive to identify or implement the actions required to achieve regulatory goals.
- Regulators may struggle to monitor and assess the extent to which businesses' actions are consistent with regulatory goals and hold businesses accountable where they are not.

A more prescriptive, rules-based regulatory approach may therefore be preferable in less dynamic environments, where a consistent set of actions may be required of all businesses to achieve the regulatory goal.

These characteristics are typically not true of the Fourth Industrial Revolution and so focus is needed on how to build business capability and responsibility. In this regard, regulators should reflect on the potential to employ soft law mechanisms, such as regulatory guidance (see Section 3.3) or industry-led governance (see Chapter 6) to foster compliance and help achieve regulatory goals.

In the same regard, attention is needed to how regulators monitor performance against outcomes. Chapter 5 examines how regulatory enforcement may evolve in the Fourth Industrial Revolution, including the potential for new technologies to enable a more goal-based approach.

3.2 Including experimentation and sunset clauses in regulation

A goal-based approach to regulation may not always be appropriate or possible. For example, political or legal constraints may mean that prescriptive rules must be set, even when the technological, economic, social or environmental context is likely to change. A more rigid regulatory framework need not necessarily be a barrier to agility. A number of jurisdictions have introduced regulatory devices intended to help ensure that regulation adapts to change, such as experimentation clauses and sunset clauses.

Experimentation clauses

Experimentation clauses are used to permit derogations from a regulation to enable alternative

approaches to be taken, with the aim of learning how the regulation may need to adapt in the future.²⁴ This typically takes the form of an exemption, such as a derogation from specific requirements or from the need to seek authorization or a permit.

As for experimentation initiatives more generally, it is important to place time limits on the permitted duration of exemptions so as not to undermine fair competition between businesses. This should be sufficient to enable testing and learning, including any changes to the law necessary for the innovation to be permitted once the test has concluded. Further guidance on experimental initiatives is set out in Chapter 4.

Introducing a “right to innovate” in Italy

To enable experimentation across the Italian economy, in 2020 the Ministry for Technological Innovation and Digitalization introduced the “Diritto a Innovare”, or “Right to Innovate”.²⁵ The legal provision enables derogations from regulations that inhibit new ideas, products or business models, in order to foster the development, dissemination and use of emerging technologies and high-tech initiatives.

Innovators – including companies, start-ups, universities and research bodies – that identify a regulatory obstacle are able to ask the government for permission to experiment, through a temporary derogation from statutory regulations. The Ministry evaluates factors including the feasibility of the

proposal, the level of technological innovation and its potential economic, social and environmental impact, in conjunction with other relevant authorities. Successful proposals are granted the “right to innovate” for a specified period of time subject to certain conditions.

At the end of the experimentation period, if the trial has been successful, the Ministry evaluates whether and how to introduce revisions to regulations that would enable all businesses to benefit from the same rules. A similar approach to experimentation has been introduced in Japan,²⁶ while, in Germany, experimentation clauses have been introduced to enable experimentation in energy, media and transport.²⁷



Sunset or review clauses

Sunset or review clauses are used to ensure that regulations are reviewed at a specified point in time (or following a specified trigger) to understand whether they achieve their goals. While review clauses simply mandate a review of the regulation at the nominated point in time, sunset clauses cause the regulation to cease to have effect unless action is taken to extend the law.²⁸

While sunset or review clauses are relevant for all regulation, they may be especially useful when introducing prescriptive regulatory approaches. An analysis by Deloitte has found that 67% of all current sections of the US Code of Federal Regulations

have never been edited since they were originally created.²⁹ Sunset or review clauses can help ensure that regulation is reviewed at the right time.

The question of when a review should be set depends on the nature of the regulation. In some jurisdictions, outcome-based triggers are used to inform when regulation should be reviewed. This can help ensure that a regulation continues to achieve its outcomes or avoids undesirable impacts. In other cases, reviews are set for specified points in time. This can provide some regulatory certainty for businesses but may result in inappropriate regulation languishing on the statute books until a review is due.

3.3 Using soft law to provide certainty for business

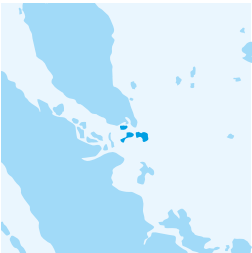
While a goal-based regulatory approach can provide flexibility for businesses, it can also introduce uncertainty as firms assess whether their actions will be considered sufficient to achieve regulatory goals. This can lead to over- or under-compliance, depending on the risk appetite of the business.

As explained in Chapter 4, newer or smaller businesses may lack the experience or capacity to interpret complex regulatory frameworks. Non-binding instruments (soft law), such as regulatory guidance, codes of practice and voluntary standards, may be used to complement goal-based regulation

and reduce regulatory uncertainty for businesses, while providing flexibility for those that wish to innovate.³⁰ More detail on the use of industry-led governance mechanisms is included in Chapter 6.

Soft law can be more easily updated to keep pace with technological change and be more accessible and less burdensome than prescriptive regulation. As with regulation, the principles of proportionality, fairness and openness remain crucial. Outdated or excessive guidance that diverts resource into unnecessary compliance activity without achieving outcomes may be worse than having no guidance at all.

Shaping the governance of artificial intelligence in Singapore



The development and use of AI technologies can bring about many benefits – from transforming businesses and improving labour productivity, to enhancing quality of life. However, concern is increasing regarding the risk of harm associated with the use of AI technologies if they are not deployed in a responsible manner, and the data within these models is not managed properly.

In response, the Singapore Infocomm Media Development Authority developed its Model AI Governance Framework, a sector-, technology- and algorithm-agnostic framework, which translates ethical principles to implementable practices that organizations deploying AI can adopt.³¹

The Model AI Governance Framework is regularly updated in line with the evolution of the technology and business practices. Businesses are invited to provide feedback on the framework and submit use cases to help other enterprises understand how to implement AI responsibly.



3.4 | Issues to consider

Outcome-focused regulation and the foundations of good regulatory practice

As discussed in Chapter 1, the concepts of proportionality, fairness and openness are integral to the design of all regulation.

Stakeholder engagement is a crucial part of defining regulatory goals, while regulatory impact assessments can help evaluate the advantages or disadvantages of different regulatory approaches. Post-implementation reviews can help ensure that the regulation remains fit for purpose.

The same principles apply to complements to regulation, such as regulatory guidance, codes of practice or voluntary standards. In many cases, these are subject to less rigorous processes than regulation, which can lead to a proliferation of guidance that is outdated, burdensome or unfairly favours certain actors. Effort is needed to continuously improve the stock of soft law in the same way as for regulation.

Outcome-focused regulation as part of a more agile approach to regulation

Outcome-focused regulation is a prerequisite for many [experimental regulatory approaches](#). It can be challenging to test and learn from different ways of doing things without a goal-based regulatory framework or sufficient experimentation clauses.

In the same way, other aspects of agile regulation complement a more outcome-focused approach. Goal-based regulation effectively shares accountability between the regulator (which sets the goals) and businesses (which determine what actions are needed to meet those goals). [Voluntary standards](#) can help support responsible business innovation that achieves regulatory goals.

Similarly, [data-driven regulation](#) can support a goal-based regulatory approach. Where the goals set out in regulation are specific and measurable, both businesses and regulators may employ data-driven methods to optimize performance against these goals.

4 | Experimental regulation



Photo: Anna Berkut/Getty Images

Regulation has a powerful impact on businesses' ability to innovate. In one UK study, just 29% of the businesses surveyed thought that regulation enabled innovative products and services to be brought to market efficiently.³² Similar findings have been identified in other advanced economies around the world.

In this context, it is crucial that regulators find ways to engage with businesses on proposed ideas,

products and business models to learn how both parties need to adapt. This process of learning and adaptation is called "experimental regulation".

The use of such techniques is growing in the finance, digital, mobility, healthcare and energy sectors – with cross-economy initiatives emerging also. This chapter examines three approaches to experimentation: advice services, testing initiatives and regulatory challenges.

4.1 Providing regulatory advice to innovators

Clear and timely regulatory advice is vital for innovators who are developing new ideas, products and business models. Where businesses face uncertainty about whether their ideas will be considered compliant with regulation, they are less likely to be able to persuade potential investors or consumers of the merits of their innovation – and less likely to innovate.

In reality, there are often many more opportunities for innovation under existing regulations than businesses realize. New or small businesses that lack experience or capacity may find it particularly challenging to navigate complex regulatory

frameworks. UK research has found that innovative businesses are twice as likely as others to seek regulatory information and advice.³³

In response, many governments have introduced advice services for innovators to help reduce uncertainty about the regulatory implications of their ideas. These go by a variety of names, including one-stop shops, single points of contact, innovation hubs, portals and, in some cases, regulatory sandboxes (see also the next section). Examples have been found in over 50 jurisdictions around the world, in domains from energy to healthcare.

Establishing an advice service involves six steps:³⁴

Planning

Market research is essential to ensure that the service addresses the issues that businesses in the market, or those looking to enter the market, face. Issues may include regulatory uncertainty, complexity or barriers (perceived or real) and challenges in securing regulatory advice that is timely, specific and affordable. Market research should be followed by user-centred design to ensure that the service matches the needs of innovators and the dynamics of the market (e.g. response times, degree of specificity).

Access

A well-advertised, open portal is needed through which businesses can submit their queries – whether online, via telephone or face to face. It is important for this not to be excessively prescriptive or resource-intensive, so as to accommodate a diversity of businesses and ideas. Where regulatory queries are triaged, it is important for regulators to publish eligibility or prioritization criteria upfront.

Triage

Providing regulatory support is resource-intensive. Many regulators choose to prioritize which queries receive support, based on: (i) the degree of innovation relative to existing products or business models; (ii) the degree of regulatory barrier faced or support needed; and (iii) the potential for wider economic, social or environmental benefit. It is important for regulators to uphold a fair and unbiased process in choosing which businesses should receive support, based on objective criteria.

Response

To reduce regulatory uncertainty, regulators need to provide timely, clear and reliable advice. For example, regulators may choose to guarantee that initial responses will be provided within a fixed period, or to provide binding advice that provides a firm guide to their future regulatory position. Such guarantees may not be possible in rapidly evolving markets, and regulators should retain sufficient flexibility to be able to conduct their duties.

Dialogue

While in some cases regulators may simply need to explain their position, in many cases the regulator's initial response may need to be followed by a period of dialogue to enable the regulator to fully understand the opportunities and risks of the proposed idea, product or business model and the actions that the business plans to take. In some cases, the regulator and business may agree that some form of real-world test is required (see the next section).

Learning

Through engaging with and advising innovators, regulators may adapt their regulatory position or gather evidence that enables them to do so in the future. It is important for regulators to establish mechanisms for capturing this knowledge and adapting their regulatory position. In doing so, it is important that the regulator is able to adopt a consistent regulatory position when approached by businesses proposing similar ideas in the future.

Throughout the process, good governance is required to ensure that businesses are treated fairly and that protections for citizens and the environment are upheld. Regulators need to consider what skills are required to handle complex queries, what internal mechanisms are required to reach a coordinated position (including with other relevant authorities) and how the quality of regulatory decisions will be assured.

As with other experimental regulation approaches, the research on the impact of advice services is limited, but benefits may include:

- Reductions in the time, cost and complexity of introducing new ideas, products and business models, thereby increasing investment, innovation and competition
- Improvements in the extent to which new ideas, products and business models comply with regulation, thereby enhancing the protection of citizens and the environment.

To a lesser extent, advice services enable learning on the impact of regulation. To understand the impact of changes to their rules, a number of regulators now enable controlled testing of innovations under regulatory supervision.

4.2 Enabling testing under regulatory supervision

In some cases, regulation may create an unintended barrier to the introduction of new ideas, products or business models that provide economic, social or environmental benefit. Challenges can arise from both the rules themselves (whether law or regulation, formal or informal) and how they are interpreted and enforced.

By working with businesses to enable controlled testing of innovations in the real world, regulators can learn how their regulatory approach may need to adapt. As Doug Gurr, Head of Amazon UK, described: "It's a rather progressive way of thinking about this – instead of sitting there and saying we're going to write the regulation in isolation without understanding the technology, they're going to be looking over our shoulder every step of the way and they're going to develop the regulation hand-in-hand with the technology. If we do that we get better outcomes."³⁵

Such testing initiatives are often called regulatory sandboxes, test beds, laboratories, innovation spaces or experimentation programmes. This guide avoids the term "sandbox", which is also used in some jurisdictions to describe advice services.

Most testing initiatives include some degree of fixed-term regulatory relief for businesses, whether in the form of "no enforcement action" letters, temporary licences or other instruments. This enables both the regulator and the business to test different approaches to meeting policy goals over a fixed period. In many cases, regulators will require businesses to include bespoke safeguards to uphold public protections in return for this regulatory flexibility.

Similar to advice services, operating a testing initiative involves six steps:

Planning

Market research is essential to ensure that the service addresses the issues that businesses in the market, or those looking to enter the market, face. A testing initiative may not be the solution – businesses may simply need access to good regulatory advice, to understand what can be done within existing rules. Market research should be followed by user-centred design to ensure that the service matches the needs of innovators and the dynamics of the market (e.g. response times, exit from the test into the market).

Access

As with advice services, a well-advertised, open portal is needed through which businesses may apply to test new ideas, products or business models. The portal should include:

- Details of what regulatory support is on offer (advice, exemptions, etc.)
- Criteria for which businesses or ideas will be eligible for support
- A simple application process, which can accommodate a diversity of businesses and innovations
- Details of the expectations and timelines that will apply.

Many regulators accept applications only during specified windows, to enable them to manage the flow of applications, ensure that they are evaluated fairly and enable the management of the tests as a cohort. Marketing of the initiative is crucial, to gather the widest possible field of high-quality applications.

Triage

Designing and supervising trials is highly resource-intensive. Acceptance to a testing initiative is typically based on: (i) the degree of innovation relative to existing products or business models; (ii) the degree of regulatory barrier faced or support needed; and (iii) the potential for wider economic, social or environmental benefit. Many regulators will also perform due diligence on the businesses that they propose to work with, to understand their viability, compliance history and readiness to participate in tests. It is important for regulators to uphold a fair and unbiased process in choosing which businesses should receive support, based on objective criteria.

Dialogue

Regulators typically notify successful applicants within a fixed period and commence one-to-one discussions on how trials will operate (the testing protocol). This includes discussion of bespoke safeguards that will need to be put in place (either informally or formally, for example through licence conditions) to ensure that public protections remain upheld; agreement of how the trial should be communicated (e.g. to potential consumers); and confirmation of what dispute resolution mechanisms should apply. Once the trial has been agreed, regulators typically publish high-level details of the business and innovation that has been accepted for testing (without revealing commercially sensitive information), in the interests of transparency.

Testing

During the testing phase, businesses trial their innovations in line with the testing protocol. They share data with the regulator, who may offer ongoing support to help the business consider how to manage risks. Businesses are expected to communicate openly with the regulator and surface issues as soon as they arise, in return for the additional regulatory flexibility that they are given. At the end of the testing period, the outcome of the trial is evaluated and the regulator agrees with the business whether and how any restrictions may be lifted.

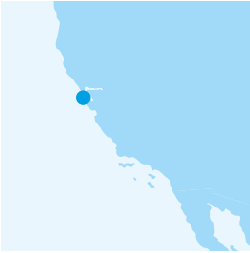
Learning

Regulatory relief provided to support a trial should be fixed-term, to ensure a level playing field for all businesses. It is therefore crucial that the regulator has a plan in place to adapt its regulatory approach for all businesses if needed at the end of the trial period, based on the evaluation of the trial. This may be straightforward in cases where exemption is provided from guidance or other forms of soft law, but requires careful planning when legislative change is required. Experimentation may need to take place in tandem with regulatory reform to avoid discontinuities between the trial period and the new regulatory regime.

Good governance is crucial. Regulators need to be able to justify why certain businesses are given support, how trials are designed (including safeguards), how risks or issues are resolved and how changes are made to their regulatory approach. As for advice services, consideration needs to be given to the skills and support that staff need to manage these complex decisions. Thought should be given to how businesses and stakeholders will be engaged in decision-making, and how decisions may be communicated to the public.

In some cases (e.g. medical or vehicle trials), a period of testing in virtual or controlled environments is required to assure safety before testing can proceed in the real world. Regulators need to consider the evidentiary threshold that they will require from such tests before they are content to authorize a real-world trial with implications for public safety.

Trialling e-scooters in San Francisco



Shared powered scooter schemes enable rapid, sustainable, individual transport but they also present safety issues and nuisance concerns. To determine how to govern this area of innovation, the San Francisco Board of Supervisors passed legislation to enable the San Francisco Municipal Transportation Agency (SFMTA) to introduce a pilot programme for trials of shared powered scooters.

SFMTA's application process invited proposals that prioritized the city's concerns about safety, equity and accountability. After thoroughly reviewing 12 applications, permits were issued to two companies to introduce a maximum of 625 scooters for the first six months, later rising to a cap of 2,500 scooters upon meeting certain criteria.

To provide transparency, SFMTA published detailed information on its decision-making process and how the success of the pilots was evaluated. At the end of the pilot programme, SFMTA issued permits to four companies in total. Permits were designed



based on learning from the pilots and included requirements on matters such as how parking would be managed and enforced, how communities would be engaged and how complaints would be addressed.

Following the conclusion of the pilot, 6,700 rides per day were being made using shared powered scooters in San Francisco.

Benefits of testing initiatives include:

- Reductions in the time, cost and complexity of introducing new ideas, products and business models, thereby increasing investment, innovation and competition
- Improvements in the extent to which new ideas, products and business models comply with regulation, thereby enhancing the protection of citizens and the environment
- Increased speed of regulatory learning and adaptation, based on a greater understanding of the opportunities and risks of new ideas, products and business models.

Testing initiatives are inherently more costly than advice services and are typically able to support fewer businesses. However, they offer much greater potential for learning and adaptation as the regulator has the opportunity to test the impact of different safeguards with participating businesses. It is therefore essential that the regulator can swiftly integrate the lessons learned from testing initiatives so all businesses can benefit from the adapted rulebook.

4.3 Setting regulatory challenges for innovators

Experimental regulation is not just used to support innovation that originates from the market. In some cases, it is used to stimulate the development of new ideas, products and business models that help achieve policy goals or missions.

The idea of running competitions for businesses to develop innovation that supports specific policy goals is well established in the field of innovation funding. It has more recently been introduced to regulatory practice where – in addition to a grant or loan to help innovators develop or introduce

their ideas – a degree of regulatory support to test novel ideas forms part of the prize.

These initiatives – often termed regulatory challenges or prizes – can be a powerful mechanism to help encourage innovation in highly-regulated markets where there are perceived barriers to entry. The idea that regulators should have an active hand in shaping which businesses succeed in the market is not without controversy, however, and careful attention is needed to the design of such initiatives to avoid inappropriate market distortion.

Most such schemes build on an established testing initiative (such as a regulatory sandbox) and comprise six phases:

Planning

In preparing a challenge, regulators need to identify a clear problem that would benefit from innovative solutions. They need to conduct engagement with innovators inside and beyond their market to understand whether there is a reasonable prospect of new ideas, products or business models entering the market, and whether additional regulatory support would unlock these opportunities. Moreover, they need to assess whether the resulting innovations are likely to succeed in the market without regulatory support after the trial.

Access

As with other regulatory experiments, an open portal is needed through which businesses may respond to the challenge. The portal should include:

- Details of what financial and regulatory support is on offer (advice, exemptions, grants, etc.)
- Criteria for which businesses or ideas will be eligible for support
- A simple application process, which can accommodate a diversity of businesses and innovations
- Details of the expectations and timelines that will apply.

Compared to other regulatory experiments, businesses may have a less well-defined idea, product or business model, and flexibility is needed in the process to accommodate this. Marketing of the initiative is essential, to gather the widest possible field of high-quality applications.

Assessment

Regulatory challenges are among the most resource-intensive experiments. Awards are typically made based on: (i) the extent to which the proposed idea addresses the challenge's goal, in a novel or innovative way; and (ii) the degree of regulatory barrier faced or support needed. Regulators will generally perform due diligence on the businesses that they propose to work with, in particular to understand their viability and innovation, and the extent to which they may succeed in the market when regulatory support ceases. As with other initiatives, it is important for regulators to uphold a fair and unbiased process in choosing which businesses should receive support, based on objective criteria.

Dialogue

Regulators typically notify successful applicants within a fixed period and commence one-to-one discussions on how their concepts will be developed and the conditions of any financial or regulatory support (as for testing initiatives). Once the award has been agreed, regulators typically publish high-level details of the business and innovation that has been accepted for testing (without revealing commercially sensitive information), in the interests of transparency.

Development and testing

Businesses then develop their ideas, products or business models, drawing on any financial or regulatory support (e.g. grants, advice, testing) provided by the regulator. While support is available only for a fixed time, time is often allowed at the start of this phase for businesses to translate their concepts into reality (in contrast to other initiatives described in this section, where businesses generally approach the regulator with proposals that are near to market). At the end of the challenge, the regulator may choose to review the innovations that have been developed (often with an independent panel) and give recognition to one or more “winners”, who have addressed the challenge particularly well.

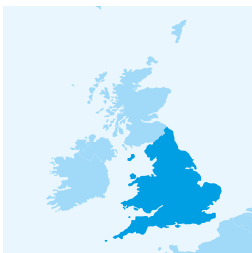
Learning

Regulatory and financial support should be fixed-term, to ensure a level playing field for all businesses. As with other regulatory experiments, regulators must reflect at the end of the experiment on what adaptations are needed to its regulatory approach. This may include adapting its approach to make it easier for other innovations to be introduced, introducing safeguards to mitigate the risks identified during the challenge, or raising performance expectations for businesses in the market that have not innovated.

As with other regulatory experiments, careful thought needs to be given to the skills that staff require, and the checks and balances that should be put in place. Concerns may be raised that the regulator is “picking winners” or risking regulatory capture through the preferential

treatment given to successful businesses. Regulators will need to be able to demonstrate that this is a focused and time-limited intervention to address a specific market failure, which does not undermine their commitment to a level playing field for all businesses.

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



In England and Wales, just one in three individuals – and one in 10 small businesses – with a legal problem get expert advice. Both the public and small businesses cite a number of barriers to using legal services, including price: 63% of people do not believe that professional legal advice is affordable for “ordinary people”.³⁶

In response, the Solicitors Regulation Authority worked with innovation foundation Nesta to set up the Legal Access Challenge.³⁷ This aimed to accelerate the development of products, services and platforms that will help individuals and small and medium-sized enterprises understand and resolve their legal problems with greater ease. In tandem, the regulator wanted to understand whether there were regulatory barriers to mass market legal technology solutions and, if so, how it might adapt its approach.

The regulator succeeded in attracting over 100 entries, often from outside the legal services sector, with coverage in the national media. Following its assessment, the regulator supported eight finalists whose innovations will make legal services more



accessible and affordable for individuals, families and small businesses. Backed by a £50,000 grant and an expert support programme, each finalist had six months to develop their solution.

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

Benefits of regulatory challenges include:

- The development and introduction of new ideas, products and business models that deliver new social, economic and/or environmental benefits
- Increased speed of regulatory learning and adaptation, based on a greater understanding of the opportunities and risks of new ideas, products and business models.

Regulatory challenges can be very costly and are able to support only a limited number of businesses. They can also be the riskiest, as they may invest in innovations that do not succeed in the market. Conversely, they are one of the few experimentation approaches focused on stimulating, rather than facilitating, innovation and can be targeted more clearly on achieving a regulator’s goals.

4.4 Issues to consider

Experimentation and the foundations of good regulatory practice

Experimental regulation can be viewed as in tension with the foundations of good regulatory practice. In particular, the provision of support by a regulator to a subset of the businesses that they regulate can be perceived to undermine the principle that regulators should design and implement rules fairly, in a way that supports a level playing field for business. Moreover, the direct regulator-to-business dialogue on an adaptation of the rules can be perceived to remove the voice of stakeholders and citizens on how safeguards should be upheld.

It is therefore crucial that regulators design and implement regulatory experiments fairly and openly. For example, many regulators strive to ensure that:

- Citizens and stakeholders are engaged at key points in the design, implementation and evaluation of initiatives.
- Initiatives are open to all businesses that meet objective eligibility criteria, and they are advertised openly.
- Support is time-limited and targeted at addressing genuine market failures (for example, the barrier to entry that regulatory complexity creates for new or small businesses).
- Enforcement is conducted at arm's length from regulatory experiments, to avoid risks of regulatory capture.
- Details of the support provided, safeguards introduced and lessons learned are made available transparently, so that others can scrutinize how experiments are conducted.

There is currently a paucity of evidence on the impact of regulatory experiments (due to both the novelty of such initiatives and, in some cases, a

lack of robust evaluation by regulators), and what is considered to be good practice in experimental regulation is likely to evolve.

Experimentation as part of a more agile approach to regulation

Experimentation should form part of a more agile approach to regulation in general. In particular:

- [Outcome-focused regulation](#) is needed to ensure that regulators have sufficient discretion to offer businesses regulatory flexibility without needing to seek frequent changes to the law.
- [Joined-up regulation](#) is needed to ensure that innovators do not benefit from regulatory flexibility in one area but remain held back by regulatory inflexibility in another.
- [International regulatory cooperation](#) is needed to ensure that innovators are not able to introduce new ideas, products and business models domestically but held back from doing so overseas.

In turn, experimentation may support the adoption of other agile regulatory practices. For example, advice services, testing initiatives and regulatory challenges may incentivize innovators to engage with the regulator, thereby making it easier to horizon-scan and anticipate technological developments.

As with the foundations of good regulatory practice, tensions between experimentation and other agile regulatory practices are possible. In particular, a trade-off exists between providing a joined-up approach across regulators and sectors (for example, a sandbox or advice hub that serves the whole economy) and the importance of tailoring initiatives to the needs of innovators in specific sectors (who may require bespoke advice or testing, to different timescales). This is explored in more detail in Chapter 7.

5 | Data-driven regulation



Photo: Alex011973/Getty Images

The advent of data-driven technologies is enabling a new approach to regulation, in which interventions may be finely targeted, outcomes may be monitored in real time and rules may be evaluated and updated at pace. The promise of achieving better outcomes at lower

cost to both businesses and regulators is tantalizing.

This chapter examines how technology is changing how regulators make and enforce rules, in ways that can deliver better outcomes.

5.1 Introducing rules as machine-readable code

Interpreting and complying with regulation is no longer only a task for humans. A growing number of businesses are translating regulations into machine-consumable formats that can be interpreted and enforced by their internal systems.

In the future, governments could produce machine-consumable versions of regulations alongside their natural language version. This idea has been described as “rules as code”, machine-consumable regulation or digital regulation. It could help reduce ambiguity in how regulation should be interpreted and make compliance faster, cheaper and more effective. For example, it could help businesses to:

- Understand what rules mean for them (e.g. by using software to visualize the implications for their business in different scenarios)
- Comply with rules with greater speed and at reduced cost (e.g. by making applications, adjusting internal controls, or providing data in an automated or semi-automated way)
- Easily demonstrate to regulators and other interested parties that they are fully compliant with rules

- Update their systems automatically in line with future changes to the rules.

As systems mature, regulators could use the data gathered to help model the effects of future changes to their code, and businesses could execute changes to their systems much more rapidly, enabling a much more agile governance system.

At present, the concept is most relevant to prescriptive, rules-based regulations that are used or implemented at scale (e.g. eligibility requirements, application processes, reporting requirements), though it may also be applied to goals-based regulation where the outcome may be precisely defined and measured. The high degree of precision required in machine-consumable regulations means that they are not generally applicable in contexts where human discretion is needed to interpret the regulation’s goals and identify the best course of action to meet these goals (see Chapter 3).

Most examples of machine-consumable regulation are pilot projects. Key steps in preparing machine-consumable regulation include:³⁸

Problem definition

At the outset, it is crucial to understand whether machine-consumable regulations can help address a given problem or demand. As noted already, digitalization is most appropriate for prescriptive, rules-based regulations that are used repeatedly by a large number of businesses. Market testing is essential to understand whether businesses would adopt machine-consumable regulations to automate their operations.

Scoping

Once a decision has been made to produce machine-consumable regulation, a range of technology choices exist – from what programming language rules should be produced in, to how machine-consumable regulations from different sources should be made interoperable. While no standard exists for how governments should prepare machine-consumable regulation, the OECD has assembled detailed guidance on factors that governments should consider.³⁹

Co-drafting

While it is possible to produce machine-consumable rules from existing regulation, it is easier to develop both in parallel, using a multidisciplinary team of policy analysts, legislative drafters, service designers and software developers. This can help reduce the gap between policy intent and its implementation, ensure that the regulation is designed with users in mind and reduce the time required to deliver regulations.

Release and adaptation

As machine-consumable regulation is still in its infancy, it is crucial that opportunity is built into pilot rules ahead of release. Consideration needs to be given to how rules should be released, including their legal status. The monitoring and evaluation of both the format and content of machine-consumable regulations is needed, so as to support rapid learning and adaptation.



Creating better rules in New Zealand with machine-consumable regulation

Digital systems can help businesses better comply with regulation. But regulation is not typically written in a language that digital systems can understand.

To address this, New Zealand's Ministry of Business, Innovation and Employment established the Better Rules initiative. In general, humans need to translate regulation into software code before it can be used by digital systems – adding risk from incorrect translation. The Better Rules initiative sought to develop regulation in both the English

language and software code in parallel during the policy development process.

The initiative brought together a multidisciplinary team of policy analysts, legislative drafters, service designers and software developers to co-design two trial pieces of regulation. It found that the process of developing machine-consumable regulation supported the development of more user-centred rules, in which the logic of the regulation was expressed more clearly. Similar initiatives have since been established in Australia and Canada.

The benefits and risks of machine-consumable regulation are debated. Beyond the business benefits outlined above, proponents of machine-consumable regulation argue that it can help reduce the gap between policy intent and implementation; reduce the need for expert interpretation of regulation and make it more transparent; and ensure that regulation is consistently and fairly applied.

Others voice fears that it could reduce business accountability for outcomes and remove human discretion in how rules should be interpreted. While machine-consumable regulation is innovative itself, care is needed to ensure that, in defining an unambiguous set of machine-readable rules, regulators do not reduce businesses' own flexibility to innovate.

5.2 Using technology to enable risk-based enforcement

The advent of data-driven technologies is reshaping not just how governments make rules, but how they secure compliance with them.

Risk-based enforcement has long been a principle of good regulatory practice. Regulators should not apply a one-size-fits-all approach to business inspections, but should target this according to the likelihood and impact of non-compliance by different businesses at a given point in time. In the same way, enforcement actions should be designed to reduce the risk of non-compliance.⁴⁰

Risk-based enforcement targets regulators' resources most efficiently towards outcomes, delivering better results for citizens and the environment at lower cost to business. It complements a more [goal-based regulatory approach](#), in which businesses may choose different paths to achieve regulatory goals.

To adopt a risk-based approach, regulators need timely, accurate and comprehensive data to help

them predict which businesses are at greatest risk of not achieving outcomes. Through the Fourth Industrial Revolution, a wealth of new technologies are emerging that support this:

- Regulators have access to more ways to **gather and process data** than ever before, including through drones, smart sensing, wearables, IoT, web-scraping and robotic process automation.
- Regulators also have access to better ways to securely **store, share and analyse data**, including through cloud computing, blockchain, big data analytics and AI.

Taken together, these developments mean that regulators are more able to target their activities in a risk-based way than ever before. However, many regulators have yet to seize the potential of these emerging technologies, with concerns about costs, systems integration and skills at the fore.⁴¹

Key steps in embarking on a regulatory technology project include:⁴²

Scoping

There will typically be many different technological solutions to a particular regulatory challenge. It is important to consider a wide range of options, including non-technological solutions and off-the-shelf options, and to regularly scan the horizon for other solutions that may emerge. Where possible, it can be helpful to engage with other regulators or organizations who have adopted similar technological solutions.

Resourcing

Before embarking on a project, it is important to consider the skills needed and the extent to which new staff or external contractors will be required. If engaging external contractors is needed, regulators should think through how to mitigate the risk of becoming dependent on their skills. Regulators should identify how both the development and the maintenance of the project will be funded, and how to scope the project in a way that matches resource availability (e.g. starting small and adding functionality).

Data management

Regulators should consider the systems and protocols that will be needed to manage data. For example, arrangements may need to be put in place to access or share certain types of data. Protocols and validation mechanisms may be needed to ensure data quality. Controls may be needed to uphold data security and protect personal or sensitive data. Novel infrastructure (e.g. cloud-based systems) may be needed to support resource-intensive data analysis.

Prototyping and testing

Where possible, regulators should develop a prototype or minimum viable product first, with the aim of building skills, demonstrating “quick wins” and securing buy-in from stakeholders. It is important to integrate user testing and feedback as soon as possible into the design process and allow sufficient time and resources for successive cycles of prototyping and testing.

Roll-out and learning

Regulators may use a combination of pioneer users, demonstration events and training to help explain the technology and demonstrate its benefits to operational staff. It is important to monitor the approach’s performance in delivering its intended benefits and use the learning to refine and improve systems and inform future technology business cases.

As with machine-consumable regulation, it can be beneficial to develop the technology needed to support the administration of regulation in tandem with developing the regulation itself.

Increasingly, regulators are using hackathons and TechSprints to help address their technology needs. Under this approach, regulators incentivize

technologists to develop proposals to address a well-defined problem where no solution exists on the market. Following review by an expert panel, the best proposals are awarded an amount of research and development funding to take the idea from concept to prototype. Further competitive rounds may be run to take proposals from prototype to final solution.

Using new technologies to enable better financial supervision

Data-driven technologies offer substantial potential to make it easier for financial services regulators to identify and address risks to consumers.

To promote the development and adoption of these technologies, the Saudi G20 Presidency and the Bank for International Settlements Innovation Hub launched the G20 TechSprint. Firms were invited to develop technological solutions that would enable dynamic information sharing, improved monitoring and surveillance, and enhanced regulatory reporting.

Private firms competed and developed innovative solutions to these problems using a cloud-based platform to support registration, prototype building and the online judging of submissions. An



independent, international panel of experts chose the winning solutions, with firms receiving cash prizes of \$50,000 for each problem solved and the opportunity to showcase their solutions at the Singapore FinTech Festival.

There are plenty of other ways in which new technologies can support a more agile regulatory approach, beyond supporting risk-based enforcement. As in other organizations, regulators are adopting technologies such as robotic process automation to streamline routine tasks like the

processing of permits,⁴³ while chatbots are being adopted in some jurisdictions to help advise businesses on regulation. Such technological solutions can help cut the cost, delay and uncertainty involved in regulatory compliance, freeing businesses up to innovate.

5.3 Issues to consider

Data-driven regulation and the foundations of good regulatory practice

Data-driven methods can support a more proportionate approach to regulation, in which the burden of compliance with regulation is minimized without compromising on outcomes. But there can be tensions with other foundations of good regulatory practice.

Machine-consumable regulation can be seen to support a more user-centred approach to regulation, as rules are expressed with greater logic and clarity. It can also be perceived as fairer, as the rules are applied in exactly the same way for all businesses. However, where machine-consumable regulation is built on prescriptive rules it may lack the flexibility to take into account the heterogeneity of different businesses and their contexts, applying a one-size-fits-all approach unless programmed otherwise.

The opposite judgement applies to risk-based enforcement, which employs a differential approach to businesses according to their risk of non-compliance. While in theory this approach upholds fairness by treating businesses with the same risk profile identically, in practice this relies heavily on the quality of the data and analysis that supports the prediction of compliance risk. Poor data or analysis can lead to businesses being

unfairly targeted. The transparency of methods and explainability of results are important.

Data-driven regulation as part of a more agile approach to regulation

Machine-consumable regulation may be perceived as agile because of the pace with which it enables businesses to interpret and comply with rules. However, where built on prescriptive rules rather than goal-based rules, it can reduce businesses' flexibility to take different approaches to achieving compliance and leave them with limited accountability. More work is needed to examine whether and how it should be applied in the more volatile, uncertain, complex and ambiguous contexts that characterize the Fourth Industrial Revolution.

Conversely, risk-based enforcement complements many of the techniques set out in this guide. By focusing on both the likelihood and impact of non-compliance, it supports a more outcome-based approach. In regulatory experiments, a data-driven approach to enforcement is essential in managing the very different risk profile of participating businesses. A risk-based approach can also reinforce and reward industry self-governance – with businesses that demonstrate responsibility benefiting from a reduced regulatory burden, as set out in the next chapter.

6 | Self- and co-regulation



Photo: Monsiti/Getty Images

In responding to the pace and complexity of the Fourth Industrial Revolution, regulators need to leverage the role that the private sector can play in the responsible governance of innovation.

Industry-led governance mechanisms, such as voluntary standards, codes of conduct and industry covenants, can help deliver policy objectives more rapidly than regulatory

intervention. The information asymmetry between businesses and regulators means that industry is typically better placed to manage the risks from technological innovation in a way that is most efficient and effective.

This chapter explores how regulators can foster responsible industry-led governance in the public interest through self- and co-regulation.

6.1 Fostering responsible industry-led governance

Industry-led governance is most successful in achieving policy outcomes where the incentives of the business align (or can be induced to align) with the goals of the regulator. A spectrum of

governance approaches can be identified, from self-regulation schemes in which the state plays little or no role, to co-regulation initiatives that are underpinned by statute:⁴⁴

| Name | Description |
|-------------|--|
| Tacit | Self-regulation with little explicit state support, though its implicit role can be influential |
| Facilitated | Self-regulation that is explicitly supported by the state in some way but where the scheme itself is not backed by statute |
| Devolved | Devolution of statutory powers to self-regulatory bodies (e.g. of occupational licensing powers to an industry council) |
| Delegated | Delegation of the implementation of statutory duties by a public authority to self-regulatory bodies |
| Cooperative | Cooperation between regulator and regulated on the operation of statutory regulation |

Industry-led governance shares many of the same characteristics of regulation. It introduces both benefits and costs for those who participate in it. Where participation becomes a *de facto* or *de jure* requirement for businesses to operate (for

example through statutory backing, buyer/consumer requirements, reputational incentives), care is needed to ensure that governance is proportionate, open, fair and agile.

Key steps in fostering the development of responsible industry-led governance include:⁴⁵

Incentives

In many cases businesses and regulators' goals will align. For example, it is not typically in a firm's self-interest to sell products that are unsafe. However, in some cases, business actions may have adverse impacts on citizens or the environment that do not affect the bottom line.

In these cases, it is important to identify what incentives could help support responsible industry-led governance. For example, governments may aim to influence:

- Target businesses by building awareness, knowledge and skills related to the problems faced
- Other businesses or trade associations to add peer pressure (e.g. by highlighting the impact that “bad apples” could have on the industry as a whole)
- Customers or buyers to make different purchasing decisions (e.g. by sharing guides on what to look for or naming and shaming poor performers)
- Financiers and shareholders to reduce their investment appetite (e.g. by releasing information on corporate responsibility)
- Citizens, civic or community groups or the media to highlight their concerns and amplify the reputational incentives for self-governance.

Such incentives generally need to balance the economic motivations that the business may have to act in a different way. Where this is not the case, governments may need to present a credible threat of regulation in order to rebalance the incentives that businesses face. In some cases, the state may need to mandate the development of industry-led governance through some form of co-regulation.

Design

The diversity of industry-led governance mechanisms means no single path to establishing these exists. For example, self-regulation frameworks may be developed by standards organizations or industry associations, negotiated by civic or stakeholder groups with businesses, or take the form of a covenant between government and industry.

Nonetheless, some principles remain key. Giving businesses a leading role in shaping self- or co-regulation can result in more efficient governance, as businesses have strong incentives to minimize compliance costs. It can also help increase business participation in such initiatives.

Ensuring that governance helps businesses respond to the incentives to change their behaviour is central. For example, for industry-led governance to address reputational pressures on businesses, it will be important for it to achieve high public awareness and credibility (e.g. through perceived independence and impact).

External oversight of the design process is necessary to ensure that governance is effective and does not suffer from “regulatory capture”. It is also crucial in ensuring that governance is open, fair and agile, and does not (deliberately or inadvertently) create unnecessary barriers to new ideas, products and business models itself (see Section 6.2).

This is especially essential where business participation in self- or co-regulation is in effect mandatory, as the process of designing industry-led governance is typically not subject to the same checks and balances as the legislative process. A regulatory impact assessment should apply to the development of co-regulation and can be a helpful discipline to integrate into the development of self-regulation initiatives.

Implementation

As with regulation, attention needs to be paid to how industry-led governance will be administered and enforced in a way that supports regulatory goals.

Self- and co-regulation initiatives that provide advice, support and expertise to businesses have been shown to improve compliance, particularly among small and medium-sized businesses that may otherwise lack the capability or capacity to comply. But building skills is not sufficient – businesses need to retain a strong economic or reputational incentive to comply long after the establishment of the initiative.

The monitoring of compliance – either by those in charge of the governance mechanism or a third party – is generally considered a prerequisite to success for self- and co-regulation initiatives. In the same regard, the threat of sanctions for non-compliance can positively impact the effectiveness and credibility of self- and co-regulation initiatives. Where such tools are used, consideration needs to be given to how disputes and appeals will be managed in an impartial and timely way.

Consideration should be given to how the underlying regulatory regime (where one exists) and approach to enforcement should adapt. For example, the development of industry-led governance mechanisms may enable regulators to shift focus from *ex ante* to *ex post* interventions.

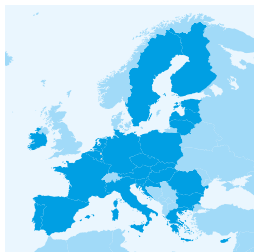
For self-regulation initiatives, regulators may incentivize compliance by reducing the regulatory burden for businesses that choose to participate in the scheme (“earned recognition”). Benefits may include reduced reporting or inspection requirements. In offering such incentives, regulators need to be confident that participation in the self-regulation initiative is genuinely correlated with a reduction in the risk of non-compliance, ideally by gathering data on this (see Chapter 5).

Adaptation

Finally, consideration needs to be given to how industry-led governance will be reviewed and updated. Freed from the legislative process, industry-led governance has the potential to be much more agile in responding to technological change and wider changes in the external environment. However, this is only true if these governance mechanisms include open and timely review processes, which enable rules to be adapted. In some cases, it may suit incumbent businesses to not evolve rules in order to uphold barriers to entry and inhibit competition.

Conversely, a lack of checks and balances may enable changes to rules to be rushed through without scrutiny or opportunity for citizens and stakeholders to provide views. Governance should be reviewed in a timely and inclusive way that supports the public interest.

Tackling online hate speech in Europe



The European Commission has worked with social media companies to ensure that hate speech is tackled online. Its e-Commerce Directive sets a goal for service providers to “act expeditiously to remove or to disable access” where they become aware of illegal activity on their platforms, but does not regulate this in detail.⁴⁶



Following the EU Colloquium on Fundamental Rights in 2015, the Commission initiated a dialogue with IT companies, in cooperation with Member States and civil society, to see how best to tackle illegal online hate speech, which spreads violence and animosity. It reached agreement with Facebook, Twitter, YouTube and Microsoft on a code of conduct that includes a series of commitments to combat the spread of illegal hate speech online in Europe.⁴⁷

Under the agreement, the companies committed to responding to the majority of valid notifications for removal of illegal hate speech in less than 24 hours and removing or disabling access to such content, if necessary. The Commission and the IT companies agreed to monitor and evaluate the impact of the code of conduct, to ensure that it remained effective.

Voluntary standards are one mechanism for formalizing industry-led governance. Put simply, a standard is an agreed way of doing things that is established by consensus and approved by a recognized body. Conformity with standards is upheld by organizations that are accredited as having the technical competence and integrity to test, certify and inspect businesses' activities.

While not all industry-led governance mechanisms can or should be expressed as standards, the use of standards can help in building trust or credibility of industry-led governance. Standards may be particularly relevant for governments seeking to co-regulate, where assurance is needed about the

process by which governance will be designed, implemented and reviewed. The International Organization for Standardization (ISO) and International Electrotechnical Commission have produced guidance on using standards to support co-regulation.⁴⁸

Voluntary standards can play an important role in enabling and stimulating innovation – from supporting the dissemination of ideas, to facilitating access to markets.⁴⁹ While often more agile than regulation, they can also face challenges in keeping pace with technological innovation if they are not developed and reviewed in a timely and inclusive way.⁵⁰ The ISO produces good-practice principles for how standards should be developed.⁵¹

6.2 Issues to consider

Self- and co-regulation and the foundations of good regulatory practice

Much like direct regulation, self- and co-regulation incurs costs in its pursuit of desired outcomes. The same foundational concepts of openness, proportionality and fairness remain vital, especially when businesses have no alternative but to comply with the rules that are set (either due to statutory underpinning or market drivers).

Industry-led governance must be transparent and support the participation of both the businesses it oversees and the stakeholders who hold an interest in it. Compared with regulation, it may be harder for citizens and stakeholders to scrutinize and influence its development, implementation and review unless mechanisms are actively designed to support it.

In the same regard, it is vital that industry-led governance is designed, administered and reviewed in a fair way, that upholds a level playing field for all businesses. Mechanisms are needed to ensure that industry-led governance does not become a deliberate or unintended barrier to competition, with rules set by incumbent businesses that may deter new ideas, products or business models.

Regulators involved in the development of industry-led governance need to consider how to support and challenge businesses to integrate ideas of openness, proportionality and fairness into these mechanisms and avoid the risk of regulatory capture. They should be especially aware of these issues when considering whether and how to give statutory backing to such schemes.

Self- and co-regulation as part of a more agile approach to regulation

As noted in Chapter 3, self- and co-regulation can be an important complement to a goal-based approach to regulation. Industry-led governance can be more accessible and less burdensome than regulation, and ensure that actions to manage risks are designed and implemented by those who are best placed to do so.

Nonetheless, care is needed to guard against unnecessarily prescriptive industry-led governance that may lack flexibility to accommodate innovation or respond to future change. As noted above, incumbent businesses

may lack incentives to update rules in an agile way where these reinforce their market position. In the same way that governments should not “regulate and forget”, regulators should make sure that [data-driven mechanisms](#) are in place to monitor the impact of industry-led governance and promote continuous learning and adaptation.

Finally, self- and co-regulation can support a more [joined-up approach to regulation](#) across regions and [nations](#), by embedding common rules across jurisdictions. This is particularly true of international standards, which may be integrated into regulation with the aim of facilitating trade.

7 | Joined-up regulation



Photo: Metamorworks/Getty Images

The Fourth Industrial Revolution is characterized by technological innovations that straddle sectors and institutions alike. Businesses can often find themselves navigating a patchwork of regulation whose complexity can deter them from introducing new ideas, products and business models. In one UK study, 69% of the businesses surveyed felt that

regulators did not work closely enough with each other.⁵²

A “whole-of-government” approach is needed to seize the opportunities and manage the risks of the Fourth Industrial Revolution. This chapter explores the strategies that regulators can employ to bridge the gap across institutions and regions.

7.1 Promoting coordination across regulators

Within all governments, regulatory functions are separated among different organizational units to permit specialization, efficiency and, in some cases, independence. However, this separation of functions can come at a cost if it results in a regulatory system that has gaps and overlaps, rendering it less effective at achieving outcomes, while adding complexity, cost and delay for business.

Coordination is essential in the Fourth Industrial Revolution, where the implications of many innovations affect multiple regulators. For example, novel financial technologies may present questions for both financial services regulation and data protection regulation. Regulators need to be able to find dynamic ways to identify common challenges arising from innovations and act jointly to develop and implement strategies to respond.

Much focus is rightly placed on how regulation is implemented, with a wave of one-stop shops and single points of contact emerging to create a unified interface for business and ensure that issues are tackled in a coordinated way.⁵³ However,

there are limits to what regulators can achieve if the need for coordination has not been considered in the design of regulation, resulting in misaligned requirements that are hard to address at the point of implementation.

Coordination can be applied to all the techniques set out in this guide. For example, the United Kingdom’s Regulatory Horizons Council takes a whole-of-government approach to identifying the implications of technological innovation, bringing together different regulators to jointly address the challenges faced. The Finnish Act on Transport Services sets outcomes for the transport system as a whole, enabling the coherent management of new forms of mobility.⁵⁴ Japan’s System of Special Arrangements for Corporate Field Tests coordinates different parts of government to enable regulatory experiments in every sector of the economy.⁵⁵

For this reason, there is no single guide to promoting coordination across regulators, though advice exists in relation to specific initiatives (e.g. establishing one-stop shops⁵⁶).

Key considerations include:

User engagement

Perfect coordination across government is neither realistic nor desirable. Regulators need to engage with businesses and other stakeholders to understand where the lack of coordination results in worse outcomes or unnecessary barriers to business. Engagement should not just extend to the identification of problems but should be used to ensure that solutions address the issues that businesses face.

Engagement with innovators is important to understand where current systems and approaches may inadvertently deter new ideas, products and business models. Regular horizon-scanning is needed, reflecting the fact that the needs for coordination may evolve as innovations emerge that necessitate new connections with different parts of government.

Leadership, governance and roles

Sustained leadership is required to tackle the barriers to greater coordination across regulators. Barriers may be practical (e.g. how coordination is financed, how data or systems are integrated, how legislation is complied with) but also cultural: working within an organizational unit is typically much easier than working across boundaries. The leadership challenge is even greater in the evolving context of the Fourth Industrial Revolution, where regulators may need to forge new partnerships in a more dynamic way to respond to changes in the external context.

Different arrangements may be required depending on whether coordination is centralized (e.g. one ministry coordinating a set of regulatory agencies) or decentralized (e.g. a partnership between two or more regulatory agencies). In either arrangement, governance is needed that represents the voices of all the organizations involved. Investment in developing a shared vision can help guide future change.

Irrespective of the arrangement reached, clarity about roles is required to avoid the gaps and overlaps that the coordination is intended to address. This will often need to be brokered in some detail; for example, determining which organization will lead on which aspect of policy development or how many days each organization will have to respond to a request for advice. In some instances, a new organizational structure may be warranted to ensure that related functions are conducted in an integrated way.

Financing, infrastructure and skills

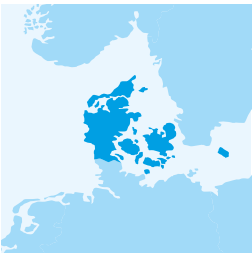
New systems may be required to support coordination, especially where the administration of regulatory functions is being coordinated. Consideration should be given to the infrastructure necessary to support such systems (e.g. shared databases) and how this will be financed and maintained. In some cases, regulators will need to consider the legal barriers to sharing information or adapting procedures.

In tandem with tackling these practical barriers, regulators should consider how to foster the skills within their organization to support coordination. As well as technical skills (e.g. an understanding of the broader implications of new technologies beyond those within their organization's competence), this includes reflecting on how to develop and reward greater collaboration.

Adaptation

As with all the techniques in this guide, it is important that adaptation is designed into any coordination initiative. This is important both to ensure that it addresses the problem it is intended to solve and remains effective in the context of external change. The monitoring and evaluation of any coordination initiative's impact – whether joint regulatory experiments or integrated regulatory enforcement – should be considered in the design from the start.

Supporting the introduction of new business models in Denmark



To help businesses ease their way through the regulatory landscape and bring their ideas to market quickly, the Danish Business Authority introduced a one-stop shop for new business models.

The service coordinates answers to innovators' questions about regulation across ministries. Businesses submit their queries through a single portal, hosted by the Danish Business Authority. The service is free of charge and has helped solve problems faced by businesses trying new things in the fields of e-commerce, the sharing economy, data and technology and the circular economy.

Businesses may also raise concerns about potential regulatory barriers to new ideas, products or business models. The Danish Business Authority works with other ministries to investigate whether



it is possible to change rules or the implementation or interpretation of the law, without undermining its objectives. It reviews how regulations are designed in neighbouring countries to identify alternative solutions.

7.2 Promoting coordination at the subnational level

In many jurisdictions, the delegation of regulatory authority from the national level to provinces, states, counties, cities and other subnational jurisdictions is substantial. Coordination is needed across and between the different levels of government to ensure that unnecessary divergence in regulatory approaches does not make it harder to achieve shared regulatory goals or to trade across localities.

This does not mean that regulation should be the same. Regulatory authority is delegated to subnational authorities in reflection of the fact that they understand best how regulation should be tailored to meet the needs of their jurisdiction. In many cases, these regulatory powers are subject to democratic oversight to ensure that they reflect local wishes and needs.

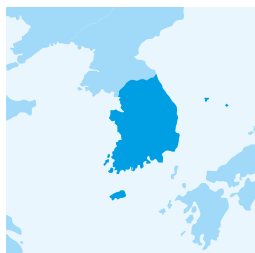
The diversity of approaches taken by subnational authorities can be a strength in identifying how to govern technological innovation. It can provide lessons about what works, which can be used to inform the development of better regulation for all, whether by national or subnational authorities.

In this regard, coordination at the subnational level should be viewed as a dynamic process of understanding the extent to which the needs of different localities can be met through common regulations or processes. This can change over time; for example, the advent of

the sharing economy has presented local regulators with greater need to work together on the implications of ride-sharing or vacation-rental platforms.

The key considerations in establishing subnational coordination initiatives are similar to those set out in Section 7.1. While, in some jurisdictions, formal mechanisms have been established to support coordination (e.g. the Canadian Free Trade Agreement⁵⁷ or Primary Authority in the United Kingdom), other jurisdictions rely on more informal dialogue to support coordination.

Testing smart city technologies in the Republic of Korea



The Republic of Korea is pioneering the development of smart city technologies to make city life more sustainable, improve citizens' quality of life and support the development of new industries. It has developed national pilot cities in Sejong and Busan to test innovations, such as mobility-as-a-service, robot-friendly infrastructure and water recycling.

As part of this initiative, in 2019 the Government introduced regulatory sandbox arrangements that permit variations to certain areas of regulation in these pilot cities.⁵⁸ Regulatory exemptions are subject to committee review and local consultation, and may be granted for a period of up to six years.



Following local trials, decisions are taken about how to adapt regulation in other regions or more generally nationwide.

7.3 Issues to consider

Joined-up regulation and the foundations of good regulatory practice

Coordination can help support a more proportionate regulatory system. While individual regulations may be designed and administered in a proportionate way, gaps and overlaps with other regulations may lead to worse policy outcomes, while creating unnecessary complexity, cost and delay. The use of common analytical approaches and models for all regulatory impact assessments can support a better understanding of the cumulative impacts of different regulations.

Regular reviews of the stock of regulation – both at the national and subnational levels – can improve the proportionality, effectiveness and coherence of the regulatory system. They can also support the adoption of a more outcome-focused regulatory approach, as overlapping rules are stripped back to the common goals that they seek to achieve, such as in the Finnish Act on Transport Services.

Openness is essential in developing a more coordinated regulatory approach. Different

regulators – whether at a national or subnational level – may have taken different approaches to respond to needs expressed by local or sectoral stakeholders. By engaging openly with businesses and other stakeholders, regulators can identify how best to make the trade-off between different policy or local objectives.

Joined-up regulation as part of a more agile approach to regulation

As noted earlier, the concept of joined-up regulation can be applied to all of the agile regulatory techniques set out in this guide – whether conducting joint horizon-scanning, developing interoperable machine-consumable regulation or integrating common technical standards into regulations developed by different states or provinces.

However, excessive coordination and bureaucracy can inhibit the pace and adaptivity that many of these techniques aim to support. An equilibrium must be reached, in which the needs for pace and coordination are appropriately balanced.

8

International regulatory cooperation

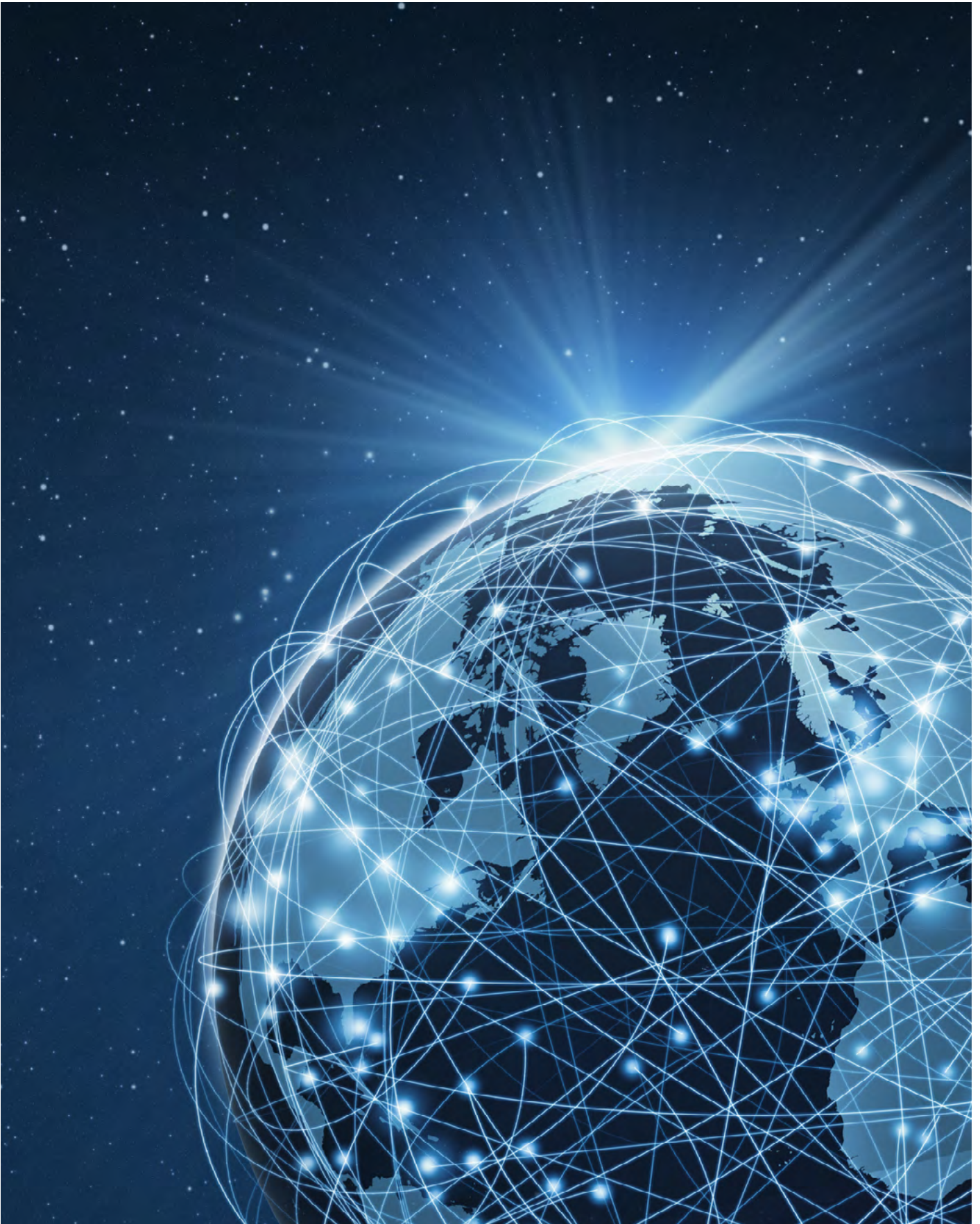


Photo: Maxiphoto/Getty Images

The Fourth Industrial Revolution is reshaping business the world over, creating common opportunities and risks that regulators in different jurisdictions must respond to.

By cooperating across borders, regulators can address these challenges more efficiently and effectively. For example, they can share knowledge, pool resources and take joint action to achieve their regulatory goals. Many digital innovations in particular are inherently cross-border, with firms able to switch between different jurisdictions at low cost while retaining a global customer base. Cooperation between administrations is needed to ensure that protections are upheld.⁵⁹

International regulatory cooperation is also crucial to facilitate trade and investment. Where regulatory approaches diverge, businesses can face additional costs to understand requirements, adjust specifications and demonstrate compliance with overseas regulations.⁶⁰ This can increase the cost of trade, ultimately leading to higher prices and fewer choices for consumers.

This chapter explores the different strategies that governments are pursuing to support international regulatory cooperation in the Fourth Industrial Revolution.

8.1 Collaborating across borders on regulation of innovation

Many different forms of international regulatory cooperation on innovation exist, including:⁶¹

Unilateral alignment

Regulators may unilaterally align with other governments' regulations or adopt international standards. For example, the [Danish Business Authority's one-stop shop](#) for new business models conducts "neighbour checks" to understand how innovations are governed in neighbouring jurisdictions as part of the process of developing its own regulatory approach.

Bilateral, plurilateral or multilateral cooperation

Regulators may decide to align their rules or approaches through mutual recognition agreements, free trade agreements, multilateral organizations or more informal partnerships. For example, [Japan's Ministry of Land, Infrastructure, Transport and Tourism](#) works through the UNECE World Forum for Harmonization of Vehicle Regulations (WP29) to agree on technical standards for autonomous vehicles.

Supranational institutions

The European Union (EU) and other supranational institutions have the power to make laws that take precedence over national law. For example, the EU's Innovation Deals for the Circular Economy⁶² sought to identify regulatory obstacles to green products or services and make recommendations for regulatory reform.

Regulators may employ a mix of international regulatory cooperation strategies to achieve their goals.

Providing more timely access to new drugs and medical devices in Canada⁶³



Health Canada aims to give people faster access to the drugs and medical devices they need, while ensuring that they are safe, effective and of good quality.

In support of this ambition, Health Canada seeks to make greater use of overseas regulatory decisions to support access to products otherwise not available in Canada. It is also examining the potential for joint reviews of new drugs and medical devices with overseas regulators to increase efficiencies and expertise in the review process.

This builds on Canada's participation in the Access Consortium, which includes regulators from Australia, Singapore, Switzerland and the United



Kingdom. Companies that submit applications to some or all of the five Access Consortium countries benefit from having their products evaluated for marketing in those countries simultaneously with reduced evaluation times.

In determining whether and how to pursue international regulatory cooperation, the improved ability to manage risks across borders, increases in trade and investment and greater administrative efficiency must be set against coordination costs, lower regulatory flexibility and reductions in regulatory sovereignty. Extensive guidance is available from the OECD to help regulators develop their approach.⁶⁴

The Fourth Industrial Revolution creates particularly fertile opportunities for regulatory cooperation, as discussion centres on how to develop new frameworks rather than how to harmonize or mutually recognize existing regulations (which may be more contentious). In this context, regulators are finding new ways to cooperate, including through sharing foresight and joint experimentation. Such activities can create the conditions for regulators to develop more interoperable and effective rules.

Supporting fintech businesses to scale across markets

New financial technologies are changing the way people invest, insure and even pay for things, prompting a wave of regulatory experimentation. Over 50 regulators around the world have established some form of fintech hub, sandbox, lab or similar arrangement to guide technological development.

However, the financial system is inherently global. Divergent approaches to the governance

of fintech can add cost and slow innovation without necessarily improving protections for consumers. Regulators in different regions of the world are finding new ways to collaborate on fintech regulation.

Many financial regulators have established regulatory cooperation agreements (“fintech bridges”) to facilitate joint work on innovation. For example, the Monetary Authority of Singapore has established 33 cooperation agreements since 2016, covering activities such as sharing foresight, evidence and support to help innovators navigate rules in each other’s jurisdiction.⁶⁵

Building on this trend, 29 regulators came together in 2019 to establish the Global Financial Innovation Network.⁶⁶ Among other things, the network is piloting an environment that will allow firms to simultaneously trial and scale new technologies in multiple jurisdictions. Separately, such cross-border sandbox arrangements have already been developed by a coalition of seven Pacific Island nations.⁶⁷



8.2 Issues to consider

International regulatory cooperation and the foundations of good regulatory practice

International regulatory cooperation can support a more proportionate approach to regulation, in which goals are achieved more effectively and at lower cost to both businesses and the state. It can also introduce coordination costs and inflexibility.

Regulatory policy tools, such as regulatory impact assessments and post-implementation reviews, should systematically examine these issues to support decisions about possible regulatory convergence or divergence. In the same fashion, stakeholder consultation should be open to both foreign and domestic stakeholders to enable regulators to gather both views and evidence on the potential impact of more or less divergent regulatory approaches.

Where regulations are developed, administered or reviewed at the international level, it is important that proportionality, openness and fairness be upheld during the process. Regrettably, many international organizations do not apply the same practices as governments do, routinely failing to engage the public, assess the impact of regulatory proposals or evaluate their success.⁶⁸ In developing new arrangements to respond to the opportunities

and challenges of the Fourth Industrial Revolution, such concepts should be integrated as a baseline.

International regulatory cooperation as part of a more agile approach to regulation

As with joined-up regulation, international regulatory cooperation can be applied to almost all of the agile regulatory techniques set out in this guide. While at present such cooperation tends to be concentrated in areas such as fintech, the newly-established Agile Nations regulatory cooperation network provides for cooperation between regulators in Canada, Denmark, Italy, Japan, Singapore, the United Arab Emirates and the United Kingdom on matters from foresight to enforcement and in domains from green technologies to mobility.

Conversely, the need for international regulatory cooperation must be balanced against the need for pace that such agile regulatory techniques enable. Excessively bureaucratic or slow-moving structures may be hard to reconcile with the rate of technological change in the Fourth Industrial Revolution, and increasingly flexible and dynamic mechanisms may be required. Further work is needed to consider how international organizations should reform themselves during this era of rapid change.

Conclusion

As the speed, depth and breadth of the Fourth Industrial Revolution continues, the techniques in this guide are rapidly becoming an essential part of the regulatory toolkit. While they can be employed independently, the techniques can be mutually reinforcing and regulators are encouraged to consider them in conjunction.

In the same way, regulators should use the techniques in this guide dynamically – adapting their approach as the external context evolves. For example, as innovations emerge, existing regulatory regimes may be too rigid and greater space for experimentation may be needed. But as technological innovation slows, the need for

predictable and stable governance may outweigh the need for flexibility.

For now, many governments are focused on the need to bolster agility. In the last year, the governments of Finland,⁶⁹ Japan⁷⁰ and the United Kingdom,⁷¹ among others, have developed strategies to introduce a more agile, innovation-enabling approach to regulation across government. Implicit in these strategies is the need to adapt the culture of regulators as well as their mechanisms, with initiatives such as Canada's Centre for Regulatory Innovation and the United Kingdom's Regulators' Pioneer Fund designed to foster change.

Promoting regulatory experimentation across government

Regulators can face a range of barriers in adopting a more agile approach to regulation. Issues can include the cost of establishing agile regulatory initiatives, the skills and systems needed to operate them and concerns about the risks implicit in novel approaches.

To address these issues, the UK Department for Business, Energy & Industrial Strategy established a £10 million competitive fund for regulatory initiatives that would help businesses bring innovative products and services to market.

Fifteen winning projects were awarded up to £1 million over 18 months to introduce their initiative, with agencies required to fund the initiative's subsequent continuation.

The fund was heavily oversubscribed, with projects supporting innovations from AI-powered medical devices to smart shipping. Projects were required to monitor and evaluate their impact, with a regulators' innovation network established to help disseminate learning and promote reform across the whole regulatory system.

While initial results are promising, many of the techniques described in this guide are too novel to be supported by significant evidence. In deploying them,

regulators are encouraged to monitor and evaluate their impact and to contribute to the development of this exciting field of regulatory practice.

Contributors

The World Economic Forum Agile Regulation for the Fourth Industrial Revolution project, in collaboration with the Government of the United Kingdom, is a global, multistakeholder and cross-disciplinary initiative intended to help shape the governance of technological innovation in the context of the Fourth Industrial Revolution. The project has engaged

leaders from governments, private companies, civil society organizations and academia to understand the merits of different approaches to regulation. The opinions expressed in this publication may not correspond with the opinions of all members and organizations involved in the project.

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