REGULATORY HORIZONS COUNCIL

Closing the gap:

getting from principles to practice for innovation friendly regulation

Summary report

Contents

Executive Summary 3

Background 7

Introduction 8

Closing the gap 9

Focal points 10

Focal point 1:
Regulation should adopt a proportionate approach to risks and benefits 11

Focal point 2:
Regulation and innovation should embrace ethics and public engagement 13

Focal point 3:
Regulation should take account of commercial considerations and the need to attract investment 15

Focal point 4:
Regulatory design and implementation should consider alternative forms of regulation 16

Focal point 5:
Regulation needs to get the timing right 18

Focal point 6:
Regulators should foster a culture of openness and a growth mindset 20

Case studies 22

Return to home

Executive Summary

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

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

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

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

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

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

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

Regulators and policymakers appreciate the impact that their work has on innovation. Their work is complex, they face competing priorities and have finite resources. In this report we aim to provide

Return to home

practical help to enable regulators and policymakers to be more supportive of technological innovation. Through our discussions with innovators, academics, and commentators, as well as with regulators and policymakers we have identified six 'focal points' for those involved in regulatory design and implementation and provide case studies in support of each. We believe focus is needed on:

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

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

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

- This asks regulators and policymakers to acknowledge that they make value judgements in their work and recommends that they be explicit about the framework they use and factors they consider in reaching those judgements. This improves transparency and predictability, and enables others to challenge those frameworks, for example where they are based on assumptions that no longer hold true.
- Regulators need to guard against being unduly influenced by arguments against change. Including barriers to entry coming from existing technologies and business models with a vested interest in the status quo and good political connections. A more open, accessible, inclusive engagement process will help to ensure that regulatory design and decision-making is not unduly influenced (consciously or unconsciously) by old technologies, to the detriment of innovation. This requires regulators and policymakers to think carefully about how they conduct public engagement. They must recognise that who, how and when they engage will have a significant impact on the conclusions they draw from public engagement.

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

- This asks regulators and policymakers to understand not only the uses of new technology but also how it will secure investment and create a proposition that is commercially viable. Only with this understanding, which needs to be grounded in business reality rather than theory, can regulators and policymakers properly take account of the impact they have on innovators.

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

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

Return to home

Focal Point 5: **Regulation needs to get the timing right**

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

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

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

Regulation is not all about regulators and policymakers. Regulation is a process of interaction between regulators and those they regulate (and wider society). We will not achieve a regulatory environment that is more enabling of innovation only by seeking change on the part of regulators and policymakers. It is important that innovators play their part too. They can do this by seeking themselves to understand and adapt to potential public concerns, and adopting responsible innovation approaches, such as those set out by the British Standards Institution and the OECD in respect of neurotechnology. This in turn should provide regulators and policymakers with confidence that innovators are taking wider considerations into account, making dialogue more constructive and potentially leading to less direct regulatory intervention.

In summary our recommendations are:

Regulators and policymakers should:

- always include cost-benefit analysis and regulatory impact assessments when evaluating the impacts on innovation. This should be taken into account in deciding whether and how to regulate. We highlight types of regulatory interventions that are likely to have an impact on technological innovation and recommend that alternative approaches be considered. (Recommendation 3)
- develop tools for broader and deeper stakeholder and public engagement and do more to share learning and best practice in the use of these tools. This could involve joint work across regulators and with experts in the field. (Recommendation 5)
- make more use of collaboration and co-creation and do more to share experiences, with a view to develop best practice in the use of these tools. (Recommendation 12)

Return to home

- make more use of adaptive regulatory tools, such as ‘sandboxes’ and ‘scaleboxes’, and do more to share learning and best practice in the use of these tools. (Recommendation 9)
- undertake horizon scanning and share the results of this work across other regulators and policymakers. Including the use of existing horizon scanning work, for example, by the Government Office for Science. (Recommendation 10)
- develop and share expertise in areas that are critical for technological innovation, such as artificial intelligence, and data science. This could be done by making more or better use of existing bodies or, if appropriate bodies do not exist, creating a panel that could be used across regulators and policymakers. (Recommendation 11)
- encourage innovators explicitly to adopt ‘responsible innovation’ approaches and take these into account in the design and implementation of regulation. (Recommendation 6)
- consider making explicit statements about the ethical frameworks that guide their decision-making, especially with respect to decisions in sensitive or contentious areas. (Recommendation 4)
- consider establishing an investor panel, including investors in disruptive technologies, which can then be used as a sounding board in the development and implementation of regulation. (Recommendation 7)
- work with appropriate bodies (such as the newly-formed Institute of Regulation) to design and provide training resources and courses for regulatory professionals on best practice on regulation and innovation. (Recommendation 2)

The government should:

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

Parliamentarians and civil society groups and other relevant bodies should:

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

Innovators should:

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

Return to home

Background

What we hope to achieve

This is a summary of the Regulatory Horizons Council's report on 'Closing the gap': Getting from principles to practices for innovation-friendly regulation. Please find the full version with recommendations here.

The Regulatory Horizons Council recognised that there have been many attempts by government and non-government actors to distil a set of principles or codes, either for 'good' regulation broadly (e.g., the Regulators' Code) or more specific regulatory principles for regulating technological innovation (e.g., Deloitte, Nesta, the Organisation for Economic Co-operation and Development). In light of this, it was felt that the most relevant – and indeed urgent – question to address was: What are the main gaps between regulatory principles and practice in relation to innovation, and how can they best be closed?

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

This report highlights case studies to bring to life regulatory principles for innovation in practice and show how some of the gaps we identify can be closed. We hope to prompt regulators and policymakers to reach out to others. We want to provide innovators or civil society groups with useful prompts for discussion with regulators and policymakers, including holding them to account for following good practice. The report could also help innovators and civil society groups to better understand the concerns and approaches of regulators and policymakers. A better-informed dialogue can only improve the regulatory process to the benefit of all.

Call to action

We hope to continue sharing examples of good practice, and we encourage regulators, policymakers, civil society groups and innovators to share further case studies with us, so we can incorporate them in a 'living' document intended to keep the conversation going.

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Introduction

Why innovation matters

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

Why regulation matters for innovation

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

Themes for existing principles for better regulation

There is no shortage of principles that relate to how regulation should be designed and implemented, domestically and internationally. These are covered in greater detail in our main ‘Closing the gap’ report.

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

- **Collaboration:** The uncertainty associated with how innovations are adopted heightens the importance of engaging with other regulators, the public, academia, businesses (incumbents and new entrants), innovators, and international bodies in the design and implementation of regulation.
- **Retaining a degree of proportionality and adaptability:** Regulation that is proportionate by taking account of both risks and benefits is often cited as important. The fast-moving nature of technological innovation creates a need for continuous regulatory experimentation, learning and adaptation.
- **Outcomes-focused:** Several publications highlight the importance of taking an outcome-focused approach, with an emphasis on avoiding prescriptive regulation where appropriate, and the usefulness of non-legislative measures such as standards.
- **Future-facing:** A final key theme revolves around being proactive in anticipating and monitoring future technological innovations, and considering possible regulatory implications in advance, if any.

Return to home

Closing the gap

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

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

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

- be proportionate and balance potential benefits and risks
- integrate ethical considerations and outputs from public and relevant stakeholder dialogue
- take account of commercial considerations and the need to attract investment
- include alternative forms of regulation
- get the timing right
- cultivate a culture of openness and a growth mindset

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

Return to home

Focal points

Regulators should foster a culture of openness and a growth mindset

Regulation should be proportionate to risks and benefits

Regulation needs to get the timing right

Regulators and innovators should embrace ethics and public engagement

Regulatory design and implementation should consider alternative forms of regulation

Regulation should take account of commercial considerations and the need to attract investment

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

Why does this matter for regulation and innovation?

The principle of proportionality has a long legal and ethical history of application in the context of regulatory decision making generally. Regulatory responses should be proportional to the good that can be achieved and the harm that may be caused.

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

There is a challenge in taking a 'proportionate' approach to new technological innovation when the nature and extent of the potential risks and benefits may not be clear. This uncertainty can lead to regulatory systems becoming unnecessarily precautionary and attending disproportionately to the risks, thereby impeding innovations.

1. The assessment of risk

Regulators or policymakers must develop a nuanced understanding of the problem they are trying to solve when considering whether to introduce or change regulation, or making an intervention based on existing regulatory frameworks.

It is important to consider what harm would occur if the risk under examination crystalised. This would include an assessment of whether the harm would be large or small. Assuming other metrics remain equal, a greater harm could justify more costly (in all forms) interventions to prevent it.

It is also important to understand the nature of the potential harm. This will include whether the harm is temporary or permanent, reversible or irreversible, and whether it is something that lends itself to compensation. The scale of the harm alone is not sufficient to justify costly regulatory intervention.

It is important to identify who would suffer the harm in question. Intervention may be more justified if the groups who would suffer are less able to take steps to protect themselves against such harm, or to recover from it.

It is also important to understand the proximity and pace of the risk. Whether regulators should do nothing or maintain a watching brief is dependent on whether potential harm is imminent or far away.

Return to home

Regulators should understand the transmission mechanism – that is, the chain of events and interactions which would ultimately result in harm arising. Without understanding this, regulators and policymakers will not have visibility of the full set of options available to them to address the harm, which creates a risk of them choosing the most costly and burdensome intervention that will address it.

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

Regulators and policymakers should explicitly consider the impact that different regulatory interventions could have on innovation. This is a necessary element in applying the principle of proportionality successfully. For an intervention to be proportionate, it is not sufficient that the cost of the intervention is proportionate to the reduction in the risk of harm it would achieve. It is also necessary to consider the risk that the intervention itself poses.

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

If regulators and policymakers are to choose the most proportionate tool for the job, they must look broadly across the full range of the regulatory and policy toolkit. Some tools, such as legislation, enforcement and price controls, will be more familiar to regulators and policymakers than others, and it is easy for the familiar to become the default. In general, flexibility is more likely to support innovation than rigidity, and flexibility is often found at the softer end of the regulatory tool kit. We discuss this more under focal point 4.

It is critically important to seek out views beyond the existing players, who may have a strong interest in creating barriers to innovation, where there are new sources of competition. It is precisely these existing players who are likely to be more expert in the regulatory regime and familiar with existing relationships, which may enable them to make powerful arguments that entrench existing regulations.

3. ‘Do nothing’ is an option

We can see that doing nothing is a difficult option for any regulator or policymaker when applying the proportionality principle, especially when faced with apparent and immediate harm, but this option should be taken seriously. It does not automatically follow that regulation will mitigate the risk or lead to better outcomes.

In reality, this option is not about doing nothing. It represents a conscious choice based on an assessment that other options would risk doing significantly more harm than good. It also often means maintaining an active ‘watching brief’. This will enable an alternative course of action to be taken should the harm-benefit balance change, and allows for learning about the new technology.

Case studies

- Agile governance of self-driving cars in Japan
- EU Directive on End-of-Life Vehicles
- Forbearance: Ofcom and access prices for final mile fibre

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

Why does this matter for regulation and innovation?

Society might distrust and be reluctant to adopt new ways of doing things. Regulatory over-reaction might lead to unnecessary, more draconian regulatory interventions.

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

1. The value of an explicit ethical framework for regulation

Regulators do and should make ethical considerations. These considerations arise over questions of 'fairness', of how safe is 'safe enough' and wherever a value is placed on life for the purpose of a cost-benefit analysis. They arise whenever regulators or policymakers balance the interests of different groups in society.

Clear statements about the principles being adopted as the basis for decision making are very useful. However, where regulation is conducted with an emphasis on pragmatism, it is likely to involve greater exercise of judgement, which makes it more important to be clear about how this is being done.

We would encourage regulators to be as explicit as possible about the frameworks they use to make judgements.

2. Public engagement as a critical enabler of trust

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

The first element is who regulators engage with.

Regulators need to engage with firms they regulate to understand whether, how and to what extent their regulation will translate into behaviour change on the part of the firms. Those who are currently subject to regulation may not be best placed to help the regulator understand and adapt to innovative approaches.

Similarly, regulators' and policymakers' engagement with the public is often through civil society groups. These groups can play an important role in synthesising views and coming up with practical proposals. However, they are institutions in their own right, with their own interests which affect their advocacy. It can be easy for regulators and policymakers to become used to engaging with certain groups and to view it as a shortcut to public engagement. Different groups in society might be uniquely affected – positively and negatively – and engagement requires a much wider lens.

Return to home

The second element of this gap is how regulators and policymakers engage.

We would encourage regulators and policymakers to adjust the balance of their effort from 'talking to, explaining and getting support' more towards 'dialogue, listening to, understanding and seeking challenge'. This would improve the effectiveness of any regulatory system.

We have heard from many innovators that they consider the extent, nature and depth of their dialogue with regulators currently to be inadequate. This leaves them concerned that regulators may not understand their innovation or the implications it could have.

Our focus on technological innovation means that we are attracted to the idea of a 'deliberative space' as a mode of public engagement. This involves creating an inclusive, easily accessible space that enables wide participation.

The final element of gap relates to when regulators and policymakers engage.

The most substantive consultation is on proposals that have already been developed by regulators and policymakers. In many cases, regulators and policymakers engage widely on proposals in which they have already invested a great deal of time and effort, and which have been formed with a smaller group of stakeholders. This means that options have already been whittled down, making it harder to influence from beyond the 'choice set' and increasing the risk of path dependency in decision making.

We would encourage regulators and policymakers to engage more broadly earlier on in the design of regulation. They could improve their understanding of risks and benefits, perhaps as they relate to a new technology, as well as test their proposals on how a problem already defined should be solved.

3. Ethics and public engagement for innovators

The more innovators build ethical considerations into the process by which their idea moves into concept, start up and scale, the more regulators and policymakers will be able to step back rather than intervene. This requires innovators to be explicit about their values and how they are applying these in what they do. There are frameworks that can help innovators to do this, which are outlined in our main report.

Case studies

- Introducing a national innovation fund and 'right to innovate' in Italy
- vTaiwan process and digital democracy
- Sciencewise public dialogue on public views of modular nuclear technologies
- Data ethics framework
- Public dialogue on mitochondrial replacement treatment

Return to home

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

Why does this matter for regulation and innovation?

Enablers of investment and commercial success are not sufficiently understood and considered in the design and implementation of regulation. In our experience, innovators do not see regulation as a barrier to scaling up their innovation. Innovators report that regulators and policymakers fail to appreciate the cost that regulation entails.

Innovative new businesses often sell to a more established player at the point of moving from start-up to scale because they are unable to cope with the increasing 'overhead' of regulation.

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

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

There could be merit in regulators and policymakers building more commercial and investment skills and experience into their teams. Many economic regulators do have 'investor relations' teams today. However, with scarce resource, most of their time is taken up with the larger investors in their sectors rather than engaging with disrupters.

Where organisations have boards, the inclusion of those with relevant commercial and investor experience will bring value.

Regulators and policymakers will simply never be able to bring into their own organisations the skills and experience needed to enable a good understanding of new technologies and new business models, and their in-house capability will always have to be supplemented by high-quality engagement.

One model that could be considered is that of an 'investor panel'. Many regulators in recent times have created 'consumer panels'. We see merit in a similar approach involving investors. Having an already-established panel, familiar with regulatory issues to engage in a properly challenging and relevant debate, could make it much easier for regulators and policymakers to include this perspective in their decision making. We see merit in creating panels that could be shared between regulators, where those regulators have a shared focus.

Case studies

- **Helping individuals and small businesses access legal support in England and Wales**
- **The Investment Industry Regulatory Organisation of Canada's establishment of the expert investor issues panel**

Return to home

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

Why does this matter for regulation and innovation?

This focal point often relates to choices that are made in the design of regulation – in particular, the extent to which regulation is 'rule-setting' as opposed to 'goal-setting' or 'outcome-setting'. It also relates to the form regulation takes, and whether it is set out using legislation or licences, or alternatives such as standards, codes of conduct and guidance.

The merits of alternative forms of regulation

Voluntary, informal or alternative forms of regulation has several advantages. They can be introduced faster than regulation, can evolve, can vary from sector to sector, reflecting different risks or risk appetites, can allow experimentation, and sanctions can be more flexible.

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

We see merit in avoiding the design and implementation of regulation by means of codified civil law approaches where possible. However, there are two issues with these common law approaches that must be addressed.

The first is an issue of legitimacy. The regulatory regime will only succeed in building and maintaining public trust, which is key for the adoption of new technologies, if it is seen as legitimate.

The second issue with the common law approach mooted by TIGRR is a practical one. If the potential for common law approaches to avoid the 'pacing problem' is to be realised, the decisions that create the regulatory regime need to be swift.

This leads us to consider other approaches, such as standards, guidance and best practice.

Standards

Standards, certified by industry bodies or by national and international standards bodies, are another example of an alternative form of regulation.

Standards can also be a means of achieving international co-operation and common approaches, helping to share best practice across countries and open up markets, which will support the commercial viability and investment potential of technological innovation.

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

Regulatory guidance and best practice

Within their own toolkit, regulators have the ability to issue guidance and best practice documents, which they may wish to do themselves rather than pursue a voluntary standards-led approach. Regulatory guidance and best practice documents are more flexible and easier to adapt over time, meaning they may be a more sensible and proportionate approach to technological innovation.

Guidance and best practice documents are not developed using the same processes or subject to the same rigour and legal challenge as licences and legislation. In our view, it is therefore unreasonable for regulators to claim the same level of enforceability for guidance.

Sandboxes

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

Regulatory sandboxes can be good for testing innovative products and services at a small scale, but some firms would welcome more assistance from regulators as they make the journey to scale.

Case studies

- Developing performance-based regulations for drones in Rwanda
- Testing smart city technologies in the Republic of Korea
- Setting global standards on smart cities

Focal point 5: **Regulation needs to get the timing right**

Why does this matter for regulation and innovation?

A common theme in many of our discussions with entrepreneurs and innovators has been the importance of timing in regulation, sometimes referred to as the ‘pacing problem’.

Don’t regulate too early

There are various reasons why regulating a technological innovation early in its life might be the wrong approach. One is simply the risk that too little is known to make a sensible decision. A reasonable assessment of the nature and scale of the future risk may take more data than exists early on in the life of a new technology. It may be better to wait than to regulate early and then have to make extensive revisions to the regulation.

Don’t regulate too late

Regulating too late can also be a problem. If regulation is only imposed after significant harm in relation to a new technology has become apparent, there is a risk of undermining trust in that new technology. It could also increase the risk of over-burdensome regulation as a response. In the absence of clarity from regulators and policymakers, investors are bearing the risk that eventual regulation might turn out to be different, creating sunk cost.

Regulation can get ‘out of sync’

Sometimes, it is not that regulation happens too early or too late, but that it is just ‘out of sync’ with the real world. This can have various negative effects. It results in unregulated new technologies with the risk of hazardous outcomes. Conversely, it means that old rules prevent new tools being used, as regulation designed for different technologies prevents innovations being fully realised.

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

Horizon scanning

It is important for regulators and policymakers to consider how regulation might be done with a view to getting the pacing right – or at least better.

Regulation stands a better chance of reflecting new developments if regulators and policymakers are aware of those developments. Horizon scanning should therefore be an important activity for any regulator. This can provide confidence that the relevant policy or law takes into account future developments, and conscious choices can be made about whether or how regulation should accommodate them.

Return to home

Scenario testing

We have seen some regulators and policymakers making good use of scenario testing in developing their regulatory approaches. Scenarios are not intended to be predictions. Instead, they identify drivers of change and difference that provide a view on a range of plausible future states of the world. By constructing several different scenarios, regulators and policymakers can test the robustness of different interventions in a variety of circumstances. It may not be possible, or indeed desirable, for an intervention to be robust to all future states identified, but it enables conscious choices to be made when considering the substance, form and timing of regulation in the face of uncertainty.

The timing of regulation will almost certainly be wrong in some respect. It may be too early or too late, or indeed both, so the need to choose regulatory tools that are adaptable is critically important.

Post-implementation reviews are also useful, but this requires a piece of work that, if it is to be done well, will take time and focus. Some regulators say they prefer automatic triggers for the expiry of regulation. It is easier to secure the resourcing needed to look at the question and help to challenge an inherent bias in any system towards the status quo.

Case studies

- **US-Japan medical device, Harmonisation by Doing (HBD)**
- **Ofgem's innovation sandbox service**
- **Regulation of e-scooters**

Return to home

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

Why does this matter for regulation and innovation?

Like all institutions, regulators have their own cultures, which influence what is done and how it is done. It is important to consider not only the substantive or formal aspects of regulation, but also the people and culture.

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

1. Skills and experience

Regulators will inevitably be less familiar with new technologies, so are at risk of regulating in ways that do not appreciate how they work, the conditions that are needed for their economic success, their benefits, or the risks they pose. Regulators can improve their understanding of technological innovations by inviting people in to speak and demonstrate, organising visits and perhaps accepting secondees.

The use of platforms, which bring together different players, co-ordinating, informing, and learning from multi-lateral interactions over time, has the potential to disrupt many sectors. We think it would be sensible to consider developing a way for regulators to access expertise in these areas. This could be achieved by building out the roles of existing bodies so that they explicitly include a role or objective to aid regulators. Our view is that a lot could be achieved by means of the right conversations at the right time.

Public engagement is a further area where competent expertise is sought after. A panel of experts on public engagement could be established to provide support across regulators, and to help regulators learn from each other.

2. Collaboration and co-creation

We believe that if the business of regulation were to become more collaborative and co-creative, regulation would be more enabling and supportive of innovation and citizens.

Innovation is happening across the boundaries between traditionally regulated areas, and in ways that cut across sectors and change the way value chains work. This demands closer collaboration across those regulatory boundaries.

Co-creation is more than collaboration: people work together to define the problem or opportunity, conceptualise a solution and think through how it could be implemented.

Return to home

Having identified a broad issue, the regulator could convene a group of relevant stakeholders to help work out whether there is a problem or an opportunity, what regulation should be seeking to achieve, how it might achieve that, and what others might do. This may reveal scope for the benefits to be achieved without formal regulation – for example, through voluntary codes or standards-setting approaches. As we encourage regulators to be more collaborative, we also believe that regulators' engagement in international regulatory cooperation can be a key driver to harnessing innovation and scaling it up to reach new markets.

3. Growth mindset and agile approaches

In some expert cultures, there is generally a 'right answer' or a 'right way', and challenge or disruption may be dismissed. People in such expert cultures can seek to bolster their perceived expertise by over-complicating things, which can hinder engagement.

The US psychologist Carol Dweck contrasts a 'fixed mindset' and a 'growth mindset'. Broadly, someone with a fixed mindset would believe that they know how to do certain things and not others. By contrast, someone with a growth mindset would believe that challenges provide opportunities to develop, and that failure is an opportunity to learn and grow.

It is easy to see how the wrong culture within a regulator would make it hard for people to embrace innovation. Whatever the substance and form of regulation, if regulators fall victim to a fixed mindset rather than embracing a growth mindset, regulation will not embrace innovation.

Agile project management techniques are closely allied to a growth mindset. The essence of agile is that it places a high value on learning and aims to maximise the opportunities for learning throughout delivery. In our view, there is scope for regulators and policymakers to adopt more agile approaches to support more open policy development.

4. The culture and mindset of regulated firms

It is important to realise that regulation is a function of continuous interactions between regulators and those they regulate. The outcomes that the regulator is seeking to achieve are delivered by the regulated firms who respond to the rules, requirements, guidance and expectations that the regulator sets. Similarly, regulators react to the behaviour and performance of the firms they regulate. Everything we have said about the importance of a culture of openness, collaboration and growth mindset therefore applies equally to firms, innovators and entrepreneurs as it does to regulators and policymakers.

Case studies

- Financial Conduct Authority TechSprints
- Aviation industry risk management
- The Digital Regulation Co-operation Forum
- Regulatory Horizons Council retrospective, August 2019-2020

Return to home

Case studies

Case studies for Focal Point 1: **Regulation should adopt a proportionate approach to risks and benefits**

1. Agile governance of self-driving cars in Japan

Sources: World Economic Forum, Agile regulation report 2020[1]

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

What was done: To keep pace with technological development, Japan's Ministry of Land, Infrastructure, Transport and Tourism has built an agile regulatory approach. Level 3 autonomous vehicles are now allowed to run on public roads, following the revision of the Road Traffic Act in 2020. The approach 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 harmonisation (under the UNECE World Forum for Harmonisation of Vehicle Regulations – WP29)
- finalizing requirements once the technology is sufficiently distributed in the market

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

2. EU Directive on End-of-Life Vehicles

Sources: EU rules aim to make the dismantling and recycling of end-of-life vehicles more environmentally friendly[2]

1 WEF Agile Regulation for the Fourth Industrial Regulation: a toolkit for regulators

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

Return to home

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

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

- reuse and recycle up to 85% of vehicle weight
- reuse and recover at least 95% of vehicle weight

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

- creation of special technical competencies in car manufacturing companies
- creation of dismantling and recovery or recycling networks
- advances in design for dismantling and recycling
- adoption of life-cycle strategies
- material regime simplification in cars
- material competition and substitution
- advances in automotive plastic recycling
- research and development in innovative recovery technologies for automobile shredding residue
- co-operative research at the industrial level

3. Forbearance: Ofcom and access prices for final mile fibre

Sources: Promoting competition and investment in fibre networks: Wholesale Fixed Telecoms Market Review 2021-26; Ofcom updates wholesale rules to accelerate the ‘full-fibre’ rollout[3, 4]

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

What was done: In the outcome of its Wholesale Fixed Telecoms Market Review 2021-26, Ofcom updated its wholesale rules with the aim of accelerating ‘full-fibre’ roll-out. They decided not to set a price cap on fibre-to-the-premises connections, or ‘full-fibre’ as it is commonly known.

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

3 Promoting competition and investment in fibre networks: Wholesale fixed telecoms market review 2021-26

4 Ofcom updates wholesale rules to accelerate full-fibre rollout

Return to home

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

4. Introducing a national innovation fund and 'right to innovate' in Italy

Source: World Economic Forum, Agile regulation report 2020[5]

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

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

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

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

5. vTaiwan process and digital democracy

Source: Anticipatory regulation: 10 ways governments can better keep up with fast-changing industries; vTaiwan; Digital democracy: the tools transforming political engagement[6, 7, 8]

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

5 WEF Agile Regulation for the Fourth Industrial Regulation: a toolkit for regulators
6 Anticipatory Regulation: 10 ways government 10 ways governments can better keep up with fast-changing industries
7 vTiawan
8 Digital Democracy: the tools transforming political engagement

Return to home

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

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

6. Sciencewise public dialogue on public views of modular nuclear technologies

Sources: Public dialogue commences on public views of modular nuclear technologies; Public dialogue on advanced nuclear technologies[9, 10]

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

- What are participants' perceptions, hopes and concerns about the development and use of advanced nuclear technologies?
- What influences those views of advanced nuclear technologies? In light of this, what might make participants more or less open to the use of them?

9 Public dialogue commences on public views of modular nuclear technologies

10 Public Dialogue on Advanced Nuclear Technologies (ANTs)

Return to home

- What do participants think is important when considering how advanced nuclear technologies might be sited and how to use advanced nuclear technologies?

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

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

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

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

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

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

7. Data ethics framework

Sources: Data ethics framework; Updating the government data ethics framework[11, 12]

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

The framework is split into overarching principles and specific actions.

Overarching principles

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

Specific actions

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

What was done: A consultation on the framework and the National Data Strategy was launched during London Tech Week 2020, to explore whether the strategy appropriately reflected the opportunities and challenges of the digital world and considered all relevant priorities, potential trade-offs and decisions. Following the consultation, the data ethics team conducted a series of workshops with stakeholders from the public sector, academia, civil society and industry, where participants applied the framework to a fictional policy scenario and were asked to identify areas for improvement in practice. Following the workshops, participants were asked to submit further feedback through anonymous forms processed by the team. Updated content was then drafted and tested through five focus groups.

11 Data Ethics Framework

12 Updating the Government Data Ethics Framework

Return to home

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

8. Public dialogue on mitochondrial replacement treatment

Sources: White paper on the Fourth Industrial Revolution[13]

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

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

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

13 Regulation for the Fourth Industrial Regulation

Return to home

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

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

Source: World Economic Forum, Agile regulation report 2020[14]

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

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

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

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

14 WEF Agile Regulation for the Fourth Industrial Regulation: a toolkit for regulators

Return to home

10. The Investment Industry Regulatory Organisation of Canada's establishment of the expert investor issues panel

Source: Regulator asks for input on composition of new investor panel[15]

Background: The Investment Industry Regulatory Organisation of Canada (IIROC) is establishing an expert investor issues panel, aimed at adding ongoing investor input into IIROC's regulatory activities.

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

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

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

15 Regulator asks for input on composition of new investor panel

Return to home

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

11. Developing performance-based regulations for drones in Rwanda

Source: What the world can learn from Rwanda's approach to drones[16]

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

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

Result: New businesses have been able 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.

12. Testing smart city technologies in the Republic of Korea

Sources: Smart Cities South Korea market intelligence report; The new smart city act will come into effect on the 17th; World Economic Forum, Agile regulation report 2020[17, 18, 19]

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

16 What the world can learn from Rwanda's approach to drones
17 Smart Cities South Korea: market intelligence report
18 The new smart city will come into effect on the 17th
19 WEF Agile Regulation for the Fourth Industrial Regulation: a toolkit for regulators

Return to home

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

Result: A total of 25 cases have been approved, including autonomous driving security robots, route guidance platforms for visually impaired people, safety services that use unmanned drones, and a demand-response bus, which changes routes in real time according to demand of passengers, using an app and an artificial intelligence algorithm to determine the best route,. This reduces the average waiting time of citizens by 70%, and travel time by 40%.

13. Setting global standards on smart cities

Sources: White paper on the Fourth Industrial Revolution[20]

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

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

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

20 Regulation for the Fourth Industrial Regulation

Return to home

Result: International recognition of the smart cities standards programme contributes to the UK's reputation in advanced urban services and helps shape the global market in line with established UK good practice.[21] Downloaded in over 60 countries, UK smart city standards are being adopted as international standards. Key benefits that users report include:

- the holistic nature of the standard
- a citizen-centric approach
- addressing the organisational barriers to getting real benefit out of city data and smart technologies
- being highly supportive of the city's local strategy
- not adopting a 'one size-fits all' approach
- flexibility to meet local needs
- providing a common framework for action across multiple city stakeholders
- the modular and pragmatic structure of ISO 37106, which means cities can choose where to start, then implement further aspects of the standard over time
- reduced risk

In China, the world's largest smart cities market, the British Standards Institution has set up a co-operation agreement on smart cities with the Standards Administration of China, to develop a common approach to smart cities between UK and Chinese cities and companies.

21 Smart Cities

Return to home

Case studies for Focal Point 5:
Regulation needs to get the timing right

14. US-Japan medical device, Harmonisation by Doing (HBD)

Source: US/Japan regulatory collaboration[22]

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

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

- **scientific sessions –** HBD organises scientific sessions along with annual conferences to promote regulatory convergence and to discuss advances in cardiovascular technology
- **global cardiovascular device clinical trials –** HBD has a workgroup focused on moving Japanese and US clinical study sponsors and regulators to the use of a single clinical trial protocol rather than parallel country-specific ones, meaning that the US could accept data from Japanese clinical studies and vice versa
- **registries –** HBD has a workgroup focused on standardising information available in post-market data registries, and reducing manufacturers' pre-market data requirements by using post-market data – this workgroup is developing an international consortium of cardiovascular registries to bring together registry information from multiple countries

Result: Some examples of products approved by the Food and Drug Administration and the Pharmaceuticals and Medical Devices Agency via the HBD pathway include:

- Cook Ireland's Zilver PTX drug-eluding peripheral stent, approved in November 2012
- Terumo Medical Corporation's Misago peripheral elf-expanding stent system, approved in May 2015
- Cardiovascular Systems, Inc's' orbital atherectomy system, approved in March 2017
- Medtronic's harmony transcatheter pulmonary valve, approved in March 2021

22 US/Japan Regulatory Collaboration

Return to home

15. Ofgem's innovation sandbox service

Sources: Ofgem innovation sandbox service[23]

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

What was done: Ofgem launched the regulatory sandbox service in 2017, and two windows have now been run in February 2017 and October 2017 respectively. 67 expressions of interest were received across the two windows. Ofgem found that many innovators required support to better understand the rules of the energy sector, and in most cases provided feedback on how these innovators could go ahead without a sandbox. Three sandboxes were enabled during the first window, and four in the second window.[24, 25] Through both windows, Ofgem gained insights and found ways to evolve their service:

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

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

23 Innovation Sandbox Service Overview
24 Innovation Link: Outcome of sandbox window 1
25 Innovation Link: Enabling trials through the regulatory sandbox

Return to home

16. Regulation of e-scooters

Sources: Regulating electric scooters (e-scooters); Illegal use of private e-scooters on the rise[26, 27]

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

What was done: It is legal to buy and sell e-scooters privately, but it is illegal to ride them on public roads, pavements and cycle lanes. Owners can ride them on private land with the owner's permission. E-scooters are classed as motor vehicles as defined by Section 185 of the Road Traffic Act 1988. All motor vehicles must have certain characteristics, including, tax, MOT, lights and number plates, but e-scooters do not meet these requirements. This means that riders could face a £300 fine and six points on their licence if they use them on public roads or pavements. However, their popularity is increasing. For example, in November 2020, the retailer Halfords reported a 71% rise in sales of e-scooters after the announcement of the second lockdown.[28] In London, the Metropolitan Police has seized more than 3,600 privately owned e-scooters in 2021.[29] Between January and June 2021, 258 collisions involving e-scooters were also recorded.

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

26 Regulating electric scooters (e-scooters)
27 Illegal use of private e-scooters: an issue on the rise
28 E-scooter gifts should be returned to shops, Met officer says
29 London e-scooter collisions jumped in 2021

Return to home

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

17. Financial Conduct Authority TechSprints

Sources: TechSprints, Financial Conduct Authority[30]

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

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

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

- consumer access
- unlocking regulatory reporting
- financial services and mental health
- model driven machine executable regulatory reporting
- pensions
- global anti-money laundering and financial crime

As they developed each TechSprint, the Financial Conduct Authority refined their model, and have extended the TechSprints over time to include wider events and activities.

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

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

30 Techsprints

Return to home

18. Aviation industry risk management

Sources: Threat and error management; Lessons from the aviation industry; Civil Aviation Authority threat and error management[31, 32, 33]

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

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

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

- **threats –** events or errors that occur beyond the influence of the line personnel, increase operational complexity, and must be managed to maintain the margins of safety
- **errors –** actions or inactions by the line personnel that lead to deviations from organisational or operational intentions or expectations
- **undesired states –** operational conditions where an unintended situation results in reduced margins of safety

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

19. The Digital Regulation Co-operation Forum

Sources: The Digital Regulation Co-operation Forum[34]

Background: The Competition and Markets Authority, the Information Commissioners Office and Ofcom formed the Digital Regulation Co-operation Forum (DRCF) in July 2020.

The DRCF was established to ensure a greater level of co-operation, given the unique challenges posed by regulation of online platforms.

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

- **Objective 1:** Collaborate to advance a coherent regulatory approach by facilitating open dialogue and joint working, to ensure that regulation and other enforcement tools applied to the digital landscape are developed and implemented in a coherent way, and produce effective and efficient outcomes that maximise benefits for consumers across policy areas.

31 Threat and Error Management (TEM)
32 Lessons from the Aviation Industry: what can we learn for humanitarian security risk management?
33 Introduction to TEM
34 The Digital Regulation Cooperation Forum

Return to home

- **Objective 2:** Inform regulatory policymaking by using the collective expertise of the DRCF to explore emerging policy challenges in the digital space and develop solutions that inform regulatory approaches.
- **Objective 3:** Enhance regulatory capabilities by pooling knowledge and resources to ensure that all members have the skills, expertise and tools needed to carry out their functions effectively in digital markets.
- **Objective 4:** Anticipate future developments by developing a shared understanding of emerging digital trends to enhance regulator effectiveness and inform strategy.
- **Objective 5:** Promote innovation by sharing knowledge and experience, including regarding innovation in the approaches of regulators.
- **Objective 6:** Strengthen international engagement with regulatory bodies to exchange information and share best practice regarding approaches to the regulation of digital markets.

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

- responding strategically to industry and technological developments
- developing joined-up regulatory approaches
- building shared skills and capabilities

They have also released further publications, including:

- 'Embedding coherence and co-operation in the fabric of digital regulators: a summary of ideas to address barriers to co-operation and measures to strengthen digital regulatory co-operation in future'[35]
- the Competition and Markets Authority and the Information Commissioners Office's joint statement on competition and data protection law[36]
- 'Joining up on future technologies: a technology horizon scanning programme, to provide a coherent view of new and emerging digital markets and technologies'[37]

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

35 Digital Regulation Cooperation Forum: embedding coherence and cooperation in the fabric of digital regulators
36 CMA-ICO joint statement on competition and protection law
37 Joining up future technologies: Digital Regulation Cooperation Forum technology horizon scanning programme

Return to home

20. Regulatory Horizons Council retrospective, August 2019-2020

Sources: Regulatory Horizons Council team retrospective, August 2020[38]

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

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

Result: The 'went well' quadrant was the most populated, including activities involving collaboration and engagement across the team. This was identified as a way the team works particularly well. As a new organisation, there were several key learnings under the 'we learnt' quadrant, with several activities relating to the team's approach and methodology for selecting priorities. The 'do differently' quadrant included adapting to unforeseen circumstances, including policy developments, and adapting to the COVID-19 pandemic, including important lessons for making the team's approach more resilient. In the 'puzzles us' quadrant, the most substantive questions were around methodology.

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

38 Regulatory Horizons Council: Retrospective August 2019 - August 2020

Return to home