

# Making Regulation Better

## The building blocks of a new approach

Authors. This report was edited by Rachel Holloway, based on contributions by Graham Russell, Srikanth Mangalam and Christopher Hodges.

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## Executive Summary

This report, "Making Regulation Better: The Building Blocks of a New Approach", explores the key components and recommendations for developing and implementing effective regulatory systems. It delves into the concept of regulation, the building blocks for regulatory excellence, and introduces a comprehensive framework for regulatory delivery.

It explores the evolving role of regulation in changing societal needs and technological advancements. It introduces the Regulatory Delivery Model as a framework for improving regulatory outcomes. Additionally, it highlights the significance of understanding human behaviour and motivation in crafting effective regulatory strategies. Trust is a central and recurring theme. The significance of trust within regulation cannot be overstated. It is more than a desirable quality in regulation; it is an essential requirement for regulatory systems to function effectively. Trust forms the foundation upon which effective regulatory systems are built. Building and maintaining trust among all stakeholders is an ongoing process, ensuring regulations serve their intended purposes while promoting fairness, accountability, and the well-being of society.

By understanding the building blocks, regulatory delivery, and the role of scientific evidence, policymakers and regulators can work toward more efficient, accountable, and evidence-based regulatory practices. We aspire for this report to serve as a valuable resource that enhances regulatory systems and outcomes.

[Section One, \*Recommendations for Building Good Regulatory Systems\*](#), advocates constructing robust regulatory systems that effectively implement government policies and achieve desired economic, social, and environmental outcomes. It underscores the importance of regulation to achieve policy goals, examines essential components for regulatory excellence, and emphasises the alignment of laws with broader policy objectives. By adopting these recommendations, policymakers and regulators can establish a regulatory framework that is agile, accountable, and aligned with the broader goals of improving the lives of citizens, fostering business competitiveness, and safeguarding the environment for future generations.

[Section Two, \*Six Questions for a Regulator\*](#), offers a framework that regulators can utilise to address the challenges posed by the rapid pace of change and the impact of digital tools on shrinking distances, all while societal inequalities continue to widen. In this evolving landscape, communities increasingly look to the government for protection, while businesses seek reassurance and stability. The traditional approach to regulatory reform centred on the design of regulations, needs to be revised. What is urgently required is a swifter and more methodical approach. Reformers must focus on effective regulation delivery, seizing opportunities to enhance agility and efficacy. This section introduces the *Regulatory Delivery Model* as a driving force behind this transformation, serving as a valuable resource for reformers ensuring effective regulation delivery.

[Section Three, \*Basing Regulation and Regulatory Action on Scientific Evidence\*](#), delves into the critical intersection of regulation and scientific evidence, shedding light on how empirical research can inform regulatory actions. It challenges traditional assumptions about human behaviour, rule compliance, and the effectiveness of enforcement mechanisms. It presents key findings and recommendations to optimise regulatory strategies by examining regulation through a scientific lens, highlighting the need to re-evaluate traditional assumptions about human behaviour and regulation. Understanding the multifaceted nature of human motivation and compliance is essential for designing effective regulatory systems. By embracing these insights and moving away from fear-based enforcement, regulators can foster cooperation, improve regulatory outcomes, and ultimately achieve better compliance with rules and regulations. The scientific evidence is brought together to underpin the *Outcome-Based Collaborative Regulation Model*.

Please join us to discuss these issues at our conference on Monday, 20th November 2023, at Wolfson College, Oxford. Contact Hilary Evans to secure your place [hilaryreidevans@mac.com](mailto:hilaryreidevans@mac.com).

# 1 Recommendations for Building Good Regulatory Systems

Governments, especially in democratic countries, are mandated to establish and implement policies for better economic and social outcomes and thus enhance the lives of their citizens, create fair and competitive environments for businesses and protect the environment for future generations. The desired policy goals and associated economic, social and environmental outcomes are typically established through political processes whereby citizens and businesses provide their inputs and expectations of government. Multi-lateral institutions such as the United Nations (UN) have established frameworks such as Sustainable Development Goals (SDGs) to guide countries, especially low and middle-income countries, in framing policies, identifying goals and establishing desired outcomes.

Regulatory policies are one way that governments implement those policies and achieve the desired economic, social and environmental outcomes. They do so through regulations, laws and other statutory and non-statutory instruments. This chapter briefly examines the evolving role of regulation and recommends the essential elements required for an effective regulatory system to be in place to deliver the intent of regulations and, more importantly, achieve the desired outcomes associated with government public policies.

## 1.1 What is Regulation, and what is a regulatory system?

*Regulation* has a variety of meanings that are not reducible to a single concept. In the field of [public policy](#), the law refers to the promulgation of targeted rules, typically accompanied by some [authoritative](#) mechanism for monitoring and enforcing [compliance](#). Accordingly, for a long time in the [United States](#), for example, the study of regulation has been synonymous with the study of the independent [agencies](#) enforcing it. In [political economy](#), it refers to the attempt of the state to steer the economy, either narrowly defined as the imposition of economic controls on the behaviour of private business or, more broadly, to include other governmental instruments, such as [taxation](#) or disclosure requirements. The two meanings focus on the [state](#)'s attempt to intervene in private activities.

A third definition of *regulation* moves beyond an interest in the state and focuses on all means of social control, intentional or unintentional. This understanding is commonly applied in [anthropology](#), sociological studies, and [international relations](#) because it includes mechanisms such as voluntary agreements or norms that exercise social control outside the reach of a [sovereign](#) state and not necessarily as an intentional act of steering.<sup>1</sup>

Thus, different strands of regulation studies share an agreement about regulation (the state), the object (the behaviour of nongovernmental actors), the instruments (an authoritative set of rules), or the domain of application (e.g., the economy). The combined presence and interaction between the instruments (directions in the forms of laws and regulations), actors (State and non-governmental actors) and their expected behaviours, and the expected/achieved outcomes in each application domain typically define a regulatory system.

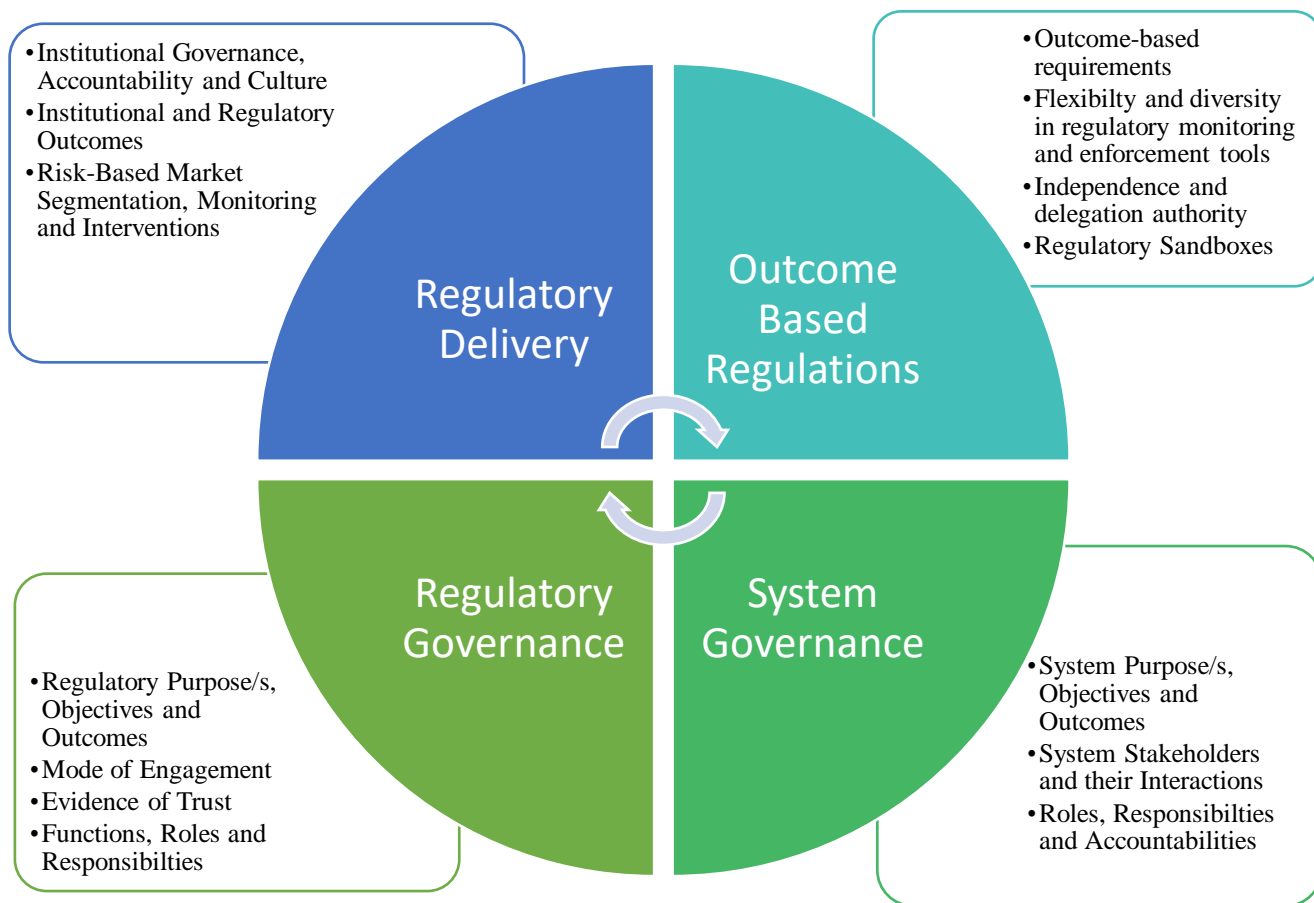
## 1.2 Building Blocks for an Effective Regulatory System

Based on the description of best practices in regulatory design and emerging thinking in regulatory delivery, including the Outcome Based Cooperative Regulation (OBCR) model<sup>2</sup>, the recommended steps for building an effective regulatory system can be illustrated by the regulatory cycle in **Figure 1**.

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<sup>1</sup> Woll, C. and Artigas, A. (2007). When trade liberalization turns into regulatory reform: The impact on business? Government relations in international trade politics. *Regulation & Governance*, 1(2), 121–138. doi:<https://doi.org/10.1111/j.1748-5991.2007.00010.x>.

<sup>2</sup> Background, Research and Concepts of OBCR are described in detail in [Section 3 of this report](#).



**Figure 1: The Regulatory Cycle**

### 1.2.1 Outcome-Based Regulations<sup>3</sup>

The OECD has researched and identified some emerging approaches for policymakers to consider in their toolkit to tackle disruption in traditional business models and supply chains. They include the following methods:

- Performance or outcome-based regulation
- Regulatory Cooperation and Collaboration
- Self-regulation and Co-regulation (Soft Regulation, Industry Codes and Standards)
- Regulatory Experiments (Regulatory Sandboxes, Adaptive Regulation).

#### 1.2.1.1 Performance or outcome-based regulation

The performance or outcome-based regulation, which typically specifies measurable outcomes (performance measures, risk thresholds, etc.), allows businesses more significant opportunities for innovation as long it is easy to demonstrate that the desired performance has been achieved. They have had a long history dating back to the early 1980s, particularly in the United States, where the focus was to relieve the regulatory burden on governments and to limit their intervention. Various forms of outcome-based regulation have since been adopted in the United States and other countries

<sup>3</sup> Sources are from various OECD meetings and documents including the SME and Entrepreneurship Ministerial Meeting 28 June 2023 <https://www.oecd.org/cfe/smes/key-issues-paper-oecd-sme-and-entrepreneurship-ministerial-meeting-2023.pdf> and OECD (2021), *OECD Regulatory Policy Outlook 2021*, OECD Publishing. <https://doi.org/10.1787/38b0fdb1-en>.

for regulating air and water quality, building and fire safety, energy efficiency, food safety, forest practices, nuclear power plants, pipeline safety, and work safety.

These regulations specify required outcomes or objectives rather than how they must be achieved. Firms and individuals can choose the process by which they will comply with the law. This allows them to identify more efficient operations and lower costs concerning their circumstances. It also promotes innovation and adopting new technology on a broader scale. The focus of regulation is shifted to outcomes rather than inputs, and the degree of government intervention in markets is effectively reduced. Adopting performance or outcome-based regulation can also simplify and clarify regulation since it can be written in terms of underlying objectives rather than requiring large amounts of detailed, prescriptive standards to be set out in legislative terms. One of the primary challenges with outcome-based regulations is the ability to administer them daily. These challenges can be addressed through clear guidance on the expectations of both the businesses and regulatory delivery professionals, such as inspectors and the approaches available to them for achieving the desired outcomes.

#### *1.2.1.2 Regulatory Cooperation and Collaboration*

Regulatory cooperation comes in many forms and types and can differ in geographical scope – from bilateral to regional or multilateral. Forms of collaboration may range from the most binding through the harmonisation of rules via joint institutions to the lightest through the exchange of information among regulators. International treaties and other formal legal agreements can impose identical legal requirements on participating nations. Still, these instruments have become increasingly challenging to negotiate and implement and, therefore, are often foregone in favour of more informal coordination approaches.

The OECD's Mutual Acceptance of Data (MAD) program, designed to address chemical safety globally, is another example of regulatory cooperation based on exchanging information and mutual recognition through an international organisation that may prove an interesting reference. In the case of the MAD framework, member nations accept one another's test data to assess new chemicals if the data are generated following the OECD test guidelines and principles of good laboratory practice. The program facilitates testing harmonisation among countries and enables burden-sharing in developing and evaluating chemical test data. By working together on technical and policy questions, members and observers understand one another's positions on issues and learn how to collectively apply technical approaches and policies to regulation.

#### *1.2.1.3 Co-Regulation*

Self-regulation typically involves a group of economic agents, such as firms in a particular industry or a professional group, voluntarily developing rules or codes of conduct that regulate or guide its members' behaviour, actions and standards. The group is responsible for developing self-regulatory instruments, monitoring compliance and ensuring enforcement. Examples of self-regulation include codes of practice, industry-based accreditation arrangements, and voluntary adoption of standards. The specific types of instruments or mechanisms that may be created under a self-regulatory regime are similar under a co-regulatory framework, but co-regulation entails explicit government involvement. The degree of government involvement and legislative backing determines the difference between the two. Self- and co-regulatory approaches are frequently used in the professions and by industry associations, where detailed technical knowledge is likely necessary.

Co-regulation can be seen as being part of the continuum between industry self-regulation and government regulation. Industry self-regulation concerns groups of firms in a particular industry or entire industry sectors that agree to act in prescribed ways according to a set of rules or principles. Participation by firms in the groups is often voluntary but could also be legally required. The groups can be wholly responsible for developing the self-regulatory instruments, monitoring compliance, and ensuring enforcement, or they can work with government entities and other stakeholders in these areas

in a co-regulatory capacity. Self-regulatory schemes entailing some degree of government involvement are typical; the level of participation, however, can vary significantly.

Confronted by the regulatory challenges posed by disruptive technologies, examples of the emergence of an amorphous system of regulatory governance called ‘Soft law’ are helpful.<sup>4</sup> The flexible nature of soft law approaches makes them relatively easy to modify in response to changing circumstances.

The International Standards Organization (ISO), the International Electrotechnical Commission (IEC), and other national standards bodies have jointly produced several international standards and guidelines covering information technology, including the specification, design, and development of systems and tools dealing with the capture, representation, processing, security, transfer, interoperability and interchange, presentation, management, organisation, storage and retrieval of information and data. Many of these standards cover a range of disruptive technologies and provide ‘soft’ but clear solutions to many regulatory challenges, such as privacy, security, interoperability, data sharing, and autonomous decisions. An example of good practices involves the power of creating alternate rules and code adoption documents<sup>5</sup> in Ontario, Canada. Ontario’s Technical Standards and Safety Act, which applies to various technical devices and infrastructure, was amended in 2021 to accommodate emerging technologies through a co-creation process<sup>6</sup> involving stakeholders. An expert panel constituted for this purpose made several recommendations, including creating powers to allow the regulator to administer alternate means to achieve the desired regulatory outcomes. In this case, the industry was expected to develop a risk management system that demonstrates a means to reduce and maintain risk at or below set acceptable levels. The Act also enables regulators to adopt national and international codes by reference to help achieve regulatory outcomes.

For agricultural applications, especially where international trade disputes are the primary concern, harmonised risk assessment and risk management principles established by an international organisation such as Codex Alimentarius are good examples of ‘soft laws’. Some of these requirements are also incorporated into regulation in some jurisdictions. For human gene editing, where medical tourism is the most significant international concern, scientific guidelines adopted by professional societies may be the best way to enforce common principles.

When faced with international governance of complex technologies constantly evolving, the current breed of soft law mechanisms serves as a foundational structure that can be built upon, which will continue to serve as new rules for emerging frontiers.

#### 1.2.1.4 Regulatory Innovations and Sandboxes

Examples of regulatory experiments that are being examined include:

- Enhancing flexibility through temporary regulation using experimental legislation, including sunset clauses to ‘define adaptable goals and enable the adjustment of laws and regulation according to the evolution of circumstances’.

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<sup>4</sup> Hagemann, R., Huddleston, J. and Thierer, A.D. (2018). Soft Law for Hard Problems: The Governance of Emerging Technologies in an Uncertain Future. *Social Science Research Network*. Note that law regimes lack ‘the mandatory, enforceable character of hard law’ and are ‘understood to shape expectations of appropriate behaviour more strongly than merely political or social undertakings.’ These may include various policy vehicles ranging from principles and codes of conduct, policy guidance documents, best practices and voluntary standards, white papers etc. Please note that ‘soft laws’ may carry a different meaning when developed by International governmental organisations such as the OECD.

<sup>5</sup> Ontario.ca. (2014). *Law Document English View*. [online] Available at: <https://www.ontario.ca/laws/statute/00t16..>

<sup>6</sup> Operating Engineers Regulatory Review Findings and Recommendations Report. (2017). Available at: <https://www.ontariocanada.com/registry/showAttachment.do?postingId=24645&attachmentId=34771> [Accessed 18 Sep. 2023].

- Creating ‘regulatory sandboxes’ allows firms to ‘roll out and test new ideas without being forced to comply with the applicable rules and regulations.’
- Developing ‘anticipatory rulemaking’ or adaptive regulation techniques that leverage feedback processes enables ‘rule-makers to adapt to regulatory contingencies if and when they arise because a feedback effect provides relevant, timely, decentralised, and institution-specific information ex-ante.’
- Utilising the iterative development of the common law to adapt rules to new technological contexts and developing new specialist regulatory agencies where they are particularly needed.
- Using ‘legal foresight’ to identify and explore possible future legal developments, discover shared values, develop shared lexicons, forge a common vision of the future, and take steps to realise that vision.
- Creating new multi-stakeholder fora to help overcome information and uncertainty issues that stifle innovation or inhibit effective regulation.

Three of these approaches are discussed below.

### **Regulatory Sandboxes**

A regulatory sandbox generally refers to a regulatory "safe space" that creates an environment for businesses to test products with less risk of being "punished" by the regulator for non-compliance. In return, regulators require applicants to incorporate appropriate safeguards to insulate the market from the risks of their innovative business. It typically involves a framework set up by a regulator to allow pilot testing of innovations by private firms in a controlled environment (e.g., exemptions, allowances, time-bound exceptions, etc.) overseen by regulators. The UK’s Financial Conduct Authority pioneered it and has provided a new way to test a new idea outside the constraints of the entire regulatory system and gain data on how well it works when applied to real scenarios<sup>7</sup>.

### **Autonomous Vehicles**

Rules for Autonomous Vehicles (AV) were introduced in Singapore in February 2017, providing guidelines for prospective trials of autonomous vehicles and automated vehicle technology. Parties announcing trials included businesses looking at autonomous bus and truck technology, ride-hailing applications, and tourist services. The AV Rules and broader legislative framework allow the Singapore Land Transport Authority (LTA) to effectively implement a regulatory sandbox with any such trial or use. The LTA, for example, creates bespoke licensing conditions and demarcated trial areas. The discretion provided to the LTA leaves it open for an applicant to engage with the LTA on the solution to be authorised. However, certain overarching conditions for authorisation and the duties of authorised operators prescribed under the Road Traffic Act and the AV Rules must be followed. A similar framework is also being adopted in Germany.

<sup>7</sup> The OECD has undertaken research on the use of sandboxes such as Attrey, A., M. Leshner and Lomax, C. (2020). *The role of sandboxes in promoting flexibility and innovation in the digital age: OECD Going Digital Toolkit Notes*, No. 2. OECD Publishing, <https://doi.org/10.1787/cdf5ed45-en>; The Financial Conduct Authority. (2022). *Regulatory Sandbox*. <https://www.fca.org.uk/firms/innovation/regulatory-sandbox>; World Bank. (2020). *Key Data from Regulatory Sandboxes across the Globe*. Online. Available at <https://www.worldbank.org/en/topic/fintech/brief/key-data-from-regulatory-sandboxes-across-the-globe>



## Canada's Approach to Novel Products

Most health products in Canada are regulated using existing rules under the Food and Drugs Act. Under exceptional circumstances, where current regulations cannot appropriately accommodate a product, a regulatory sandbox pathway has been made available. This pathway will be reserved exclusively for “Advanced Therapeutic Products,” (ATPs) which are drugs or devices that are so novel, complex, and distinct that current regulations are not equipped to handle them. ATPs can offer tremendous health and economic benefits. As more companies make use of these new technologies, it became evident for Health Canada that [a risk-based and flexible way](#) was needed to authorise these novel products, while still protecting the health and safety of Canadians. The regulatory pathway can be tailored to the specific product, addressing its unique characteristics while maintaining Health Canada’s high standards for patient safety. **Figure 2** provides a more detailed explanation of this new pathway also known as a regulatory sandbox.

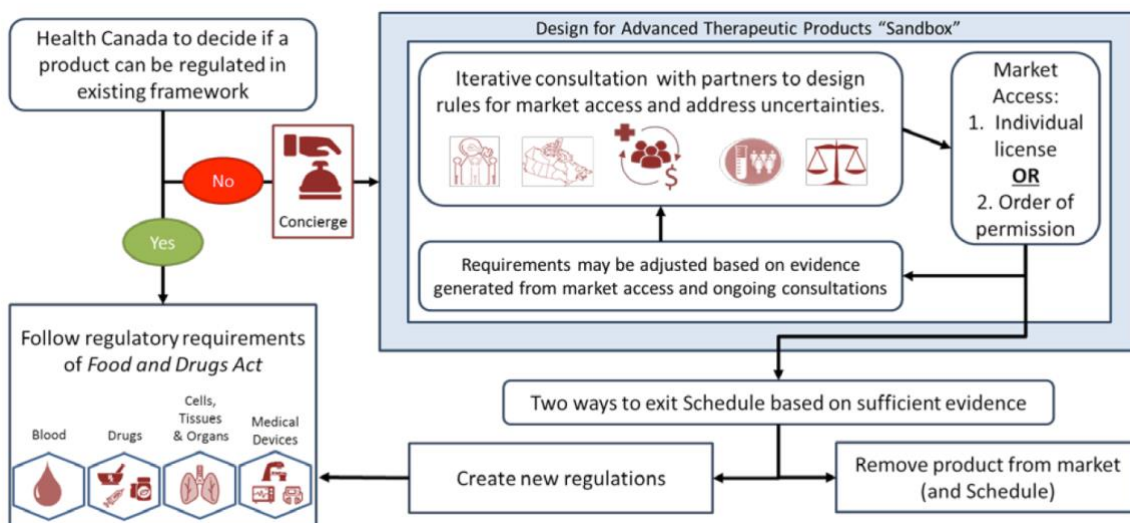


Figure 2: Health Canada's Regulatory Sandbox for Therapeutic Products

## Canada's Approach – other examples

Another variation of a regulatory sandbox involves the ability to create alternate rules, exemptions, or deviations from adopted standards and codes. [Ontario's Technical Standards and Safety Act](#), which deals with the safety of technical devices and products, provides powers to the Ministers to make any order, alternate rules, and exemptions to existing legislation in response to circumstances such as industry innovations. [Ontario's regulation on code adoption by reference](#) allows the regulatory authority to adopt and amend codes and standards to address the evolving expectations of its stakeholders and the public.

A regulatory sandbox can change the relationship between regulators and innovators toward a more open and active dialogue. This trust built on evidence will enable the regulator to revise and shape the regulatory and supervisory framework with agility. Regulators establish sandboxes to promote competition and efficiencies within markets through innovation. The success of a sandbox depends on how it is framed and the effectiveness of the innovations, amongst other factors. While the sandbox concept itself is easy to copy, its value lies in the substance of the sandbox, which is the extent to which it can promote beneficial innovation based on an in-depth knowledge exchange between the innovator and regulator. Regulatory sandboxes are good examples of ethical business regulation.

Truly smart regulation will pair the sandbox with a strong, fact-based, research-driven dispensation and licensing practice that furthers innovation while minimising risk. In doing so, these models are

recommended to be set up and operated on cooperative lines wherein contracts would be hosted based on ethical cooperation rather than traditional grant-sanction approaches. However, regulated entities benefit from responsible dispensation practices in markets where experienced regulators decide their cases while avoiding the risks and uneven competition a sandbox creates. Therefore, some large and professional regulators have hesitated to adopt the sandbox approach and seek an efficient level of forbearance or dispensation through no-action letters, restricted licensing, piloting, and other tools. Risks and limitations with regulatory sandbox include sending negative signals to markets as the sandboxes are essentially ‘unregulated’, lack of transparency and standardisation, and perceptions of not creating level playing fields.

Regulators can use regulatory sandboxes to address market innovations before the legislative process makes changes. A hybrid approach involving traditional sandbox models supported by legislative powers to create alternate rules may be a way forward for regulators to consider when dealing with industry advancements and innovations.

Adaptive regulation refers to the design of institutions and processes to review and update policies considering evolving scientific knowledge and changing technological, economic, social, and political conditions. With the pace at which technologies and business models change and evolve globally, adaptive regulation may pose challenges for regulators, regulated parties and other stakeholders. Periodic re-evaluation and revision might reduce the stability and predictability of rules, discouraging investment and innovation. The Institute of Risk Governance (IRGC) suggests planned adaptive regulation (PAR) to handle changes with more flexibility and predictability. This approach involves regularly reviewing and revising regulations instead of making a final decision that becomes outdated over time, resulting in unintended consequences and rigid rules that hinder innovation.

Regulations should be outcome-based and performance-focused, driving the right behaviours within the system. **Regulations should, at a minimum:**

- Define the expected outcomes of the rules (and, if possible, about the overall design)
- Provide clarity on the roles and responsibilities of the various stakeholders interacting with the system and
- Act as a framework that provides flexibility to regulators and regulated parties to build trust, generate evidence on performance, and intervention tools that help achieve outcomes

### 1.2.2 System Governance

Regulations typically function as intricate systems with numerous purposes and objectives. For example, the purposes and objectives of a food system may be to make healthy, safe, and nutritious food accessible and affordable to citizens using a fair, reliable, and efficient supply chain. For this example, the food system may be governed by multiple sets of regulations such as food safety, labour codes, transportation rules, measurement regulations, financial requirements, etc. The various sets of regulations may create conflicts or synergies in regulatory objectives, which can positively and negatively affect the desired purposes and objectives of the overall system. In the absence of a “super-regulation” that would accommodate the interconnectedness of the various goals/objectives, it would be beneficial to acknowledge these interrelationships while setting up regulatory frameworks for each regulation.

When designing an outcome-based regulatory framework, it is necessary and beneficial for each regulator to understand the broad purposes, objectives and aspects of the system and the stakeholders, including regulators affecting the system and their interactions. This could lead to the development of

formal or informal partnerships and cooperation across the different stakeholders to achieve the broad objectives of the system, as described in the next step of the process.

### 1.2.3 Regulatory Governance

Based on an understanding of the system in which they operate and the regulatory mandates provided to them, regulators use this process step to establish regulatory purpose/s, objectives, and desired outcomes through a co-creation process. Key outcomes of this step include:

- Identification of stakeholders willing to/required to participate in the regulatory system (aspects of the overall system governed and/or affected by regulations)
- Development of regulatory purpose(s), objectives, and desired outcomes of the regulatory system that consider but are not limited by the strict interpretation of the regulatory mandate
- Addressing potential conflicts in goals such as those between driving prosperity and increasing protection (e.g., strict performance of mandate vs. government policy)
- Establishing the mode of engagement for a trust-based system between the various stakeholders using methods such as codes of practice and including the following elements:
  - Identifying the roles, responsibilities, and accountabilities with an emphasis on creating a balance of responsibilities between the regulator and the regulated (e.g., where should the burden of proof lie)
  - Developing a set of ethical values and principles under which they will operate
  - establishing the nature of collecting and demonstrating evidence of behaviours and the means of providing feedback
  - Developing the risk frameworks to segment players based on performance
  - Options of support and intervention, including regulatory enforcement based on risk.

In some circumstances, transitioning to a fully trust-based system may not be possible and may take time. Some actors and methods may be more amenable to this transition than others. A practical solution would be to offer regulated parties to select different modes or tracks that suit their circumstances and provide proportionate regulation. One track would be the ‘trust track’; another might be ‘regulation as now’; and a third might involve modules around competence, resources and support appropriate for smaller businesses, perhaps as a pathway towards the trust track. This would form a framework for a risk-based proportionate system.

<b>Tracks to provide proportionate regulation</b>
<p><b>Trust Track</b></p> <p>Individual operators can choose to produce evidence that they can be trusted based on evidence of trust and proof of performance, KPIs and outcomes. Stakeholders should agree to collaborate on the basis of agreed values, set out in an agreed Code, as explored in <a href="#">section 3</a>. This would be a light-touch regulatory regime, even in highly complex areas, as the regulated party would accept responsibility for performing its control functions effectively on a delegated basis, conducting its control operations and producing acceptable evidence whilst applying (if appropriate, on a ‘comply or explain’ basis) normal control mechanisms such as core rules, standards, guidance, quality and safety management systems, audits, and so on. The principles of mutual engagement would apply under licence conditions or an agreement/covenant (like Primary Authority). Admission to this track would depend on performance and achieving the desired controls, evidence, and outcomes.</p>
<p><b>Intermediate Track</b></p>

This system would allow for a regulation-light regime on a modular basis, subject to their evidencing competence, resource, operational and outcome requirements. This would be relevant for SMEs and organisations building up to the trust track.

#### **Basic Track**

Operators could choose a system such as the present, with a non-trust base, and be regulated as a potentially higher risk in the usual way, involving traditional inspections, surveillance, and enforcement. This would be relevant for foreign companies unwilling to assimilate the trust track.

These tracks are all trust tracks, responding to different levels of trust evidence and segmenting regulated parties on a proportionate risk basis linked to the degree of confidence that they will achieve desired outcomes. Companies would be incentivised to deliver the proper outcomes and to improve their performance in doing this.

Regulators would retain the right at any appropriate stage to inspect, require detailed proof, and intervene on a risk basis.

#### 1.2.4 Regulatory Delivery

This step is about implementing the regulatory delivery model for the regulator to effectively oversee and deliver on their mandate using a cooperative approach and in line with the established code of practice described in the previous step. The six elements of the regulatory delivery model (governance, accountability, culture, outcome measurement, risk-based prioritisation, and intervention choices) are described in [Section 2](#) in detail.

## 2 Six Questions for a Regulator

### 2.1 Introduction to Regulatory Delivery

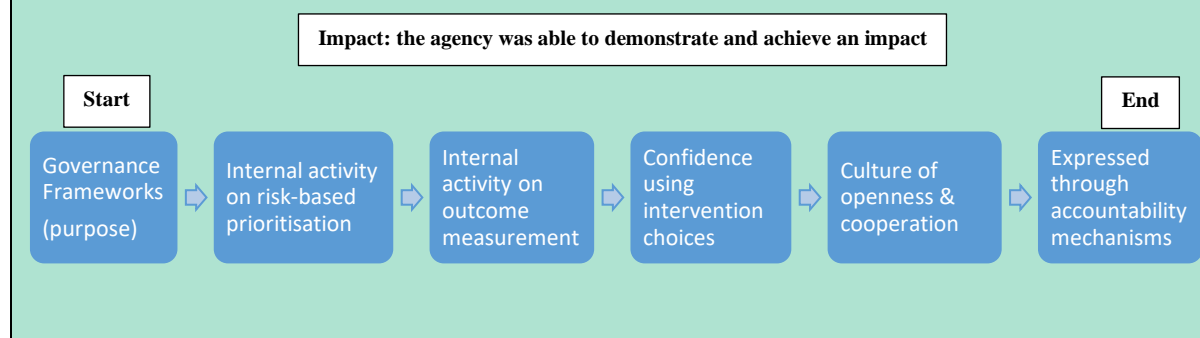
Regulation has never been more critical. The pace of change is accelerating, digital tools shrink distances, but inequalities widen; in response, communities look to the state for protection while businesses look for assurance and stability. Traditional regulatory reform, which focuses on the regulation design, does not meet these needs; it must be faster and formulaic. Reformers must address regulation delivery, seizing opportunities to be agile and effective. This section introduces the Regulatory Delivery Model as a catalyst for that change, a tool for reformers and those charged with delivery.

Regulatory delivery is how regulatory agencies operate to achieve the intended outcomes of regulation. Historically, governments and regulators have focused more on the design of rules and overlooked the importance of delivery mechanisms in securing regulatory outcomes.<sup>8</sup> The Regulatory Delivery Model (RDM) has been developed to address this inattention to delivery. It was developed by the UK Office for Product Safety and Standards to provide a framework for understanding how agencies operate and steer delivery improvements. Its development is informed by the experience of a wide range of practitioners working in different countries and academic research. The model is a tool for regulators to improve their regulatory delivery. This section briefly introduces the model and illustrates how it can be used. Further explanation and global best practice examples can be found in the book [Regulatory Delivery](#) (Russell and Hodges 2019).

#### Using the RDM in practice

An agency has received feedback that they needed more impact. The agency's Board and the Senior Leadership Team agreed that this must be explored and improved.

The RDM was used to explore the problem in a structured way, with an intentional order to identify the causes and not just symptoms. Because of its use, the agency could demonstrate how it was having an impact and improve how it was doing so.



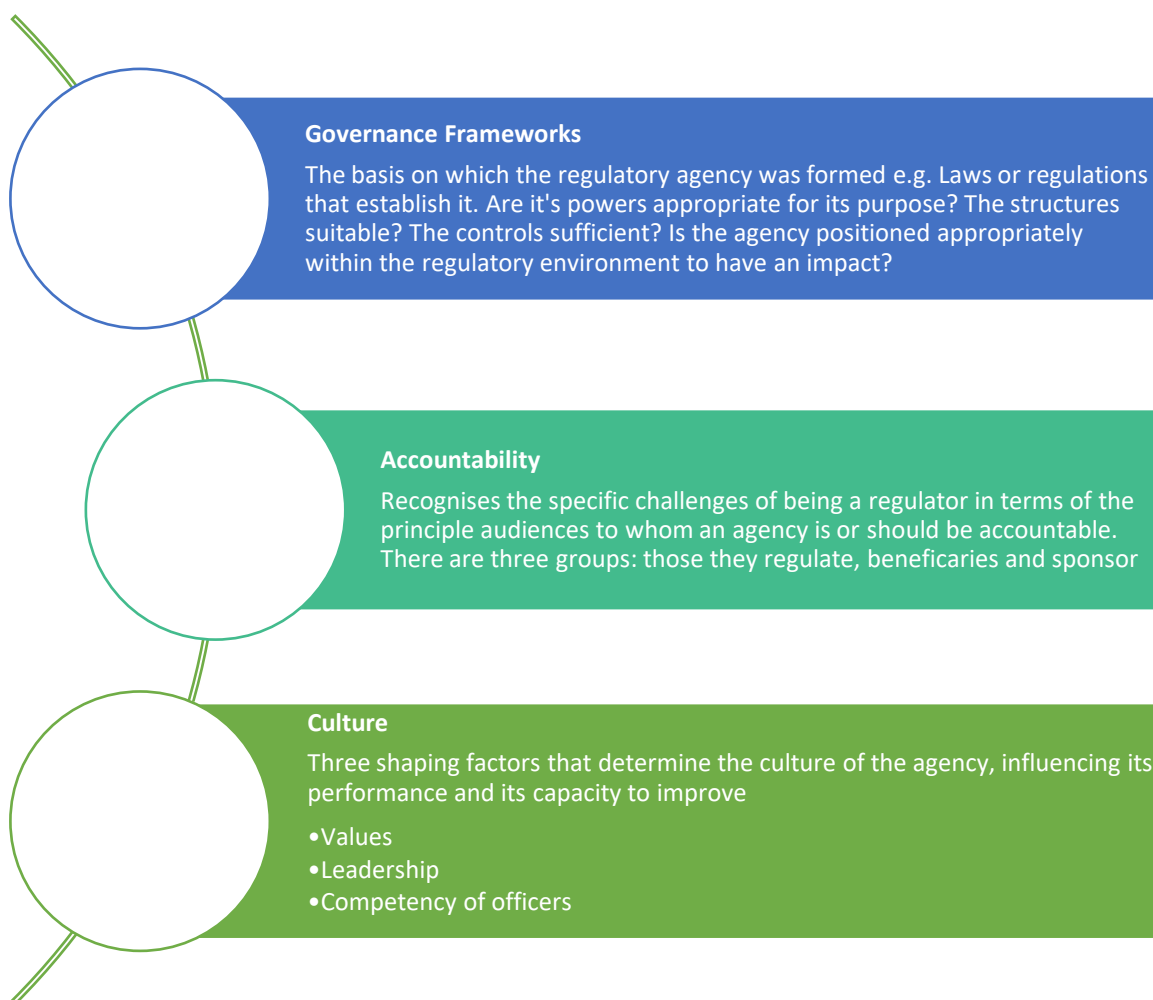
#### 2.1.1 The Elements of the Regulatory Delivery Model: The Six Questions for a Regulator

Prerequisites	Practices
Governance Frameworks	Outcome Measurement
Accountability	Risk-Based Prioritisation
Culture	Intervention Choices

<sup>8</sup> OECD and Prism Institute, *Scoping Paper on Regulatory Future of Emerging Technologies*. 2018.

### 2.1.1.1 Prerequisites

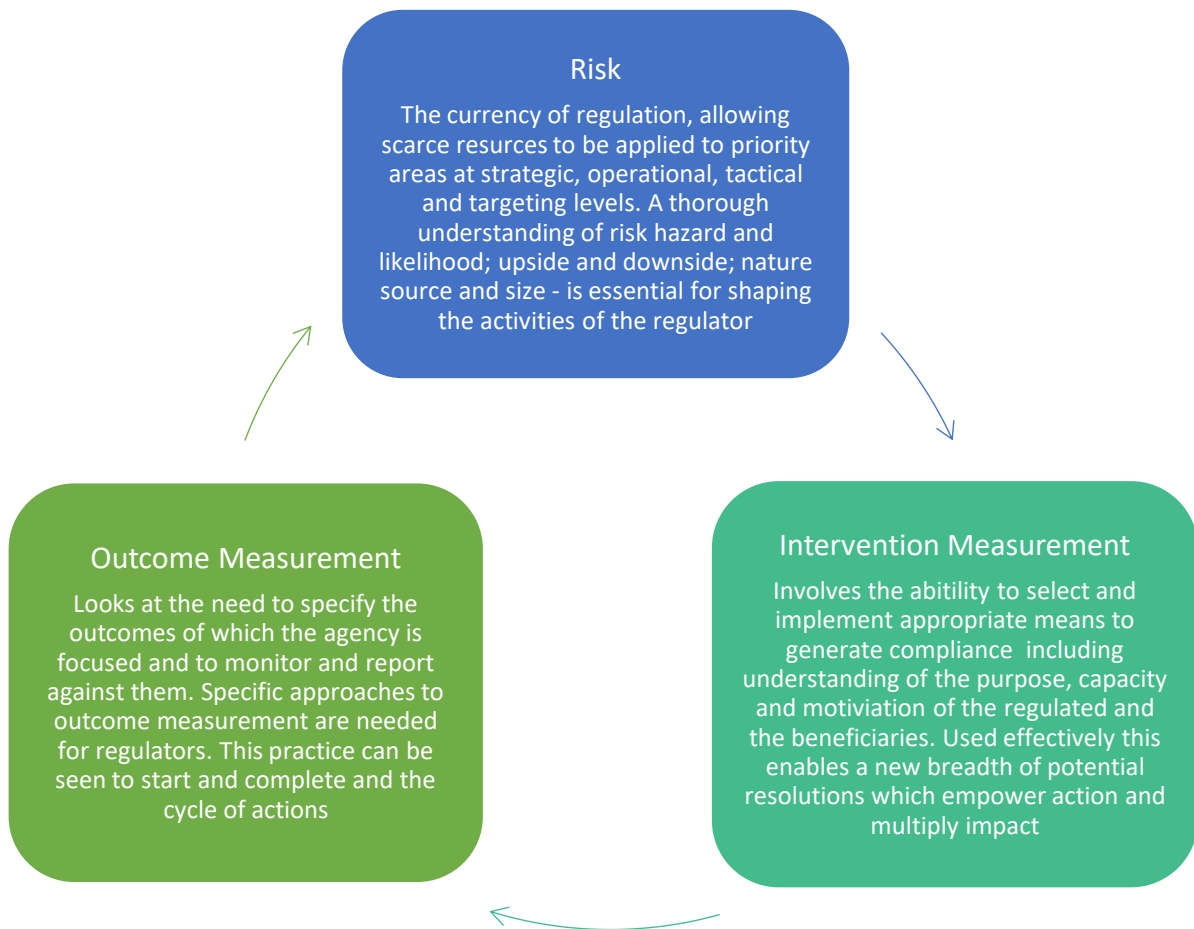
Effective regulatory systems need the right prerequisites. The question is whether the right conditions are in place for effective regulation delivery. This is addressed by examining three aspects: the governance framework within which the regulator operates, the organisation’s culture, and the operating accountability mechanisms. The components of the prerequisites are explored in **Figure 3**. A case study of how local authorities navigated ambiguity, adapted their governance frameworks and accountability and adapted their culture during COVID is set out below



**Figure 3: Building the right conditions for effective regulatory systems: the prerequisites**

### 2.1.1.2 Practices

Effective regulatory systems need the right regulatory practices (the ‘practices’). It relates to the regulator’s approach to determining its operational activities. Exploring this is addressed through consideration, often at multiple levels within the organisation, of whether the regulator is clear about the **outcomes** that it is tasked with delivering and its progress towards those outcomes, how it allocates its finite resources based on **risks** to those outcomes; and whether it is choosing appropriate **interventions** to tackle the risks that it has decided to target. The components of the practices are outlined in **Figure 4**.



**Figure 4: The optimal environment to deliver effective regulation: the practices.**

An example of the adaptation of practices to enable the provision of a sufficient amount of Personal Protection Equipment (PPE) was available – to the NHS, care homes and other businesses that need it and that PPE is safe – it protects the user is set out below.

**Personal Protective Equipment: Adapting an Existing Regulatory Regime**

Employers are responsible in the UK for ensuring their employees' safety when handling hazardous substances such as chemicals and infectious agents. This involves conducting thorough risk assessments, mitigating the risks and implementing control measures where relevant, including using Personal Protective Equipment (PPE). The COVID-19 pandemic exponentially increased the demand for PPE. Two outcomes were sought: an ongoing supply was required to help prevent the transmission of infection, and it needed to be safe for use.

*Regulatory Delivery Changes*

To deliver these outcomes, regulatory changes were instituted to expedite the supply of PPE and to provide guidance and tailored support to businesses involved in its production or importation.

A regulatory coordination cell was formed of the key regulators, the Office for Product Safety and Standards, the Health and Safety Executive and the Medicines and Healthcare Products Regulatory Agency. They oversaw changes to enable conformity assessment to be undertaken using a risk-based approach and sped up the supply of PPE.

*Enforcement*

Measures were implemented to prevent the use of hazardous PPE and discourage non-compliance. The risk model was aided by intelligence to detect potentially hazardous PPE entering the UK. The safety of imported PPE shipments was assessed by a team deployed to the NHS supply hub.

The deployment of resources led to the intercept of unsafe PPE and deterred businesses from taking a careless or criminal approach to compliance. Increased surveillance of the market was undertaken for items sold online or imported directly and this helped to monitor and regulate the quality of PPE entering the UK market.

## 2.2 Governance Frameworks

Governance is considered within the RDM as the collective set of rules and relationships defining the regulatory agency and establishing a framework within which the agency operates. Regulatory agencies are not subject to market influences and risks that drive high performance in the private sector. This brings challenges and risks in conjunction with the regulatory agency's ability to exercise the state's coercive power. A robust governance framework, with effective accountability mechanisms and an appropriate organisational culture, can address these challenges and risks and ensure the state's power is exercised appropriately.

A regulatory agency's governance framework has multiple external constituents, including the law that establishes it, its outward-facing role, and its defined relationship to others. These are part of establishing an effective authorising environment, which is further strengthened by aspects of accountability. Regulatory agencies internalise these external constituents through their strategies, policies and procedures.

The aspects of Governance Frameworks explored within the RDM are:

1. The government and legislation should **communicate the agency's purpose transparently**.
2. The regulatory **agency's structures**, such as its decision-making capability and processes.
3. The agency's position within the broader **regulatory landscape**, with clear responsibilities and appropriate arrangements for collaborating with other agencies.
4. The agency's **powers and responsibilities**, which should be appropriate to its role and purpose, should be communicated, effectively governed, and monitored.

<b>Governance Frameworks - Key Lines of Enquiry</b>
<p><b>Purpose</b></p> <ul style="list-style-type: none"> <li>▪ Has the government been clear about the purpose of the regulatory requirements and the regulatory agency?</li> <li>▪ Is the purpose well understood and agreed upon to give the agency an adequate authorising environment?</li> <li>▪ Does the agency communicate its role, purpose and objectives internally and externally?</li> <li>▪ Is the agency clear about the strength and scope of its authorisation and when and how it can be challenged?</li> </ul>
<p><b>Structures</b></p> <ul style="list-style-type: none"> <li>▪ Are the regulatory agency's shape, decision-making capability, and relationship to the government appropriate for its purpose?</li> <li>▪ As purpose changes, has the design been realigned to changing purposes [...]/?</li> </ul>



- Are the agency's internal structures, policies, procedures and decision-making processes appropriate? Do they reflect domestic and international good practices?

### **Landscape**

- Does the regulatory agency clearly understand the position of other regulatory agencies in the regulatory system – horizontal [...] and vertical [...]?
- Are responsibilities clear and distinct? With no overlap? Is simplification possible?
- Does the agency have appropriate arrangements to work collaboratively with other regulatory agencies?
- Does the agency clearly understand the other significant bodies in the regulatory system [...] and how they interact?
- Is the agency's understanding of the landscape mapped in a helpful way to the agency and others?

### **Powers and responsibilities**

- Does the regulatory agency have powers appropriate to its role and purpose?
- Are those powers established in law under local requirements and systems?
- Are those powers and any responsibilities accompanying their use communicated and understood?
- Does the agency have clear and effective internal rules determining the use of its powers, and is its operation monitored through appropriate oversight arrangements?

## Governance and accountability

The case study below demonstrates that flexibly focusing on outcomes within the regulatory framework can enable local regulators to adapt to changing risks. In response to the growing prevalence of online property listing services for sales and rentals, the National Trading Standards Estate and Letting Agency Team initiated the dissemination of vital property information to consumers.

### **Responding to Changes in How Consumers Access Property Listings to Improve the Information Provided via Online Platforms**

Online house sales and lettings have become more prevalent. In its 2021 report '[Regulation of private renting](#)', The National Audit Office found that local authorities faced barriers to understanding the regulatory tools, including insufficient staff with the right skills, limited resources and funding, and the complexity of the legislative framework. To address these challenges, The National Trading Standards Estate and Letting Agency Team (NTSELAT) was created and hosted by Bristol City Council and Powys County Council and funded by the Department for Levelling Up, Housing & Communities through a ring-fenced grant. This regulatory body oversees and enforces various laws that protect consumers and businesses in the UK. This includes regulating estate agency work under the Estate Agents Act 1979 and overseeing the enforcement of lettings agency work under the Tenant Fees Act 2019.

To improve compliance with consumer protection regulations, the team worked with property portals in the UK to improve the upfront information provided by estate and letting agents to consumers to enable them to make informed decisions. This involved agreeing on a list of key information to feature in their property listings to prevent breaches of unfair trading regulations. Making the necessary information a requirement when listing a property on online platforms helps ensure essential information is provided to consumers upfront and consistently. The objective is to

guarantee that the websites, property details, and listings of agents adhere to regulations that safeguard consumers and businesses from unjust trading practices.<sup>9</sup>

## 2.3 Accountability

In the context of regulation, accountability can be defined as ‘the obligation to account for regulatory activities to another body or person’. It is understood within the RDM in terms of the empowerment of stakeholders to participate in the regulatory process and to challenge the regulatory agency. It is essential as a constraint on the behaviour of the regulatory agency. It is also an enabler as the creation of confidence and trust strengthens the authorising environment.

The aspects of accountability explored within the RDM are:

1. The approach to **transparency** adopted by a regulatory agency, whether communications are effective and if the approach to openness builds trust.
2. Whether **mechanisms** to hold the regulatory agency to account are effective, tailored appropriately to different audiences and accessible.
3. Regulatory agencies need recognition that they are responsible for **building the capability** of those to whom they are accountable.

The RDM encourages a comprehensive consideration of accountability, with a focus on three parties in particular: the state, referred to here as ‘government’; the ‘beneficiaries’ of the regulation (referring both directly to those whom the law aims to protect and to those who articulate their concerns – whether that is groups such as trade unions representing workers or people speaking up for the environment and animals); and businesses and others that are regulated, referred to as ‘regulated entities’. **Figure 5** is a representation of some of the relationships between these parties. Accountability to regulatory agencies means different things to government, beneficiaries and regulated entities, and it is crucial to each for various reasons.

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<sup>9</sup> Adapted from The Local Government Association ‘Local authority COVID-19 compliance and enforcement good practice framework’ <https://www.local.gov.uk/local-authority-covid-19-compliance-and-enforcement-good-practice-framework#further-case-studies>, replicated with the permission of from National Trading Standards.

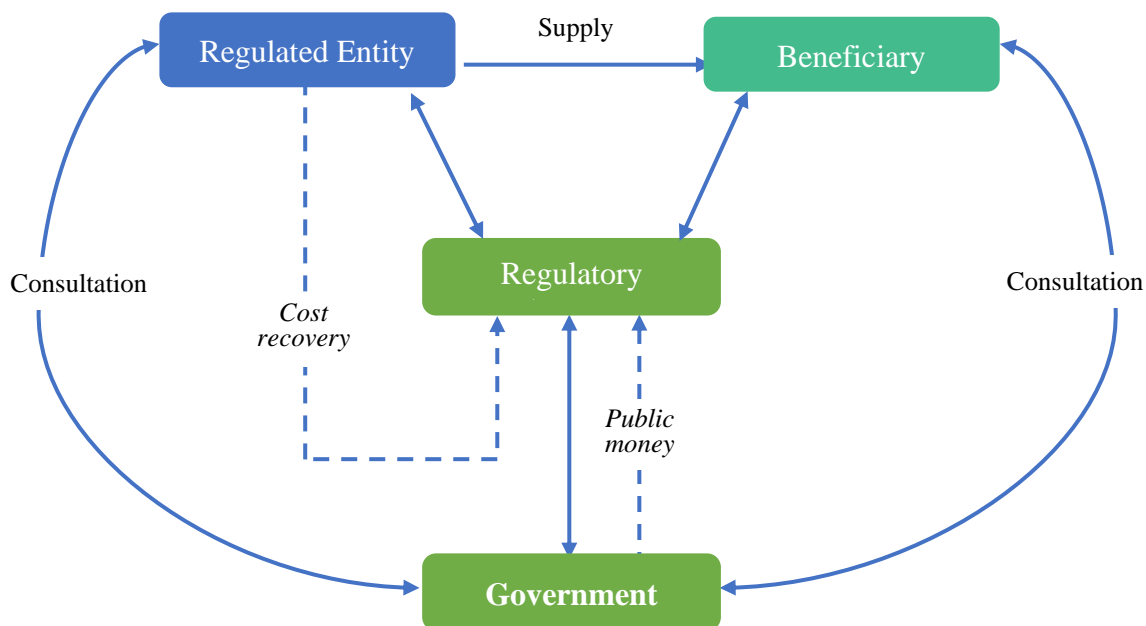


Figure 5: The relationships between the regulator and those it is accountable to

<b>Accountability - Key Lines of Enquiry</b>	
<b>Transparency</b>	<ul style="list-style-type: none"> <li>▪ Can the regulatory agency show that it has taken measures to increase the transparency of its functions and processes to regulated entities, beneficiaries and the government?</li> <li>▪ Does the agency communicate in ways that are effective for its context – including through publication but also by the use of other practical, relevant channels?</li> <li>▪ Does the agency's approach reflect domestic and international good practices?</li> <li>▪ Can the agency show that this transparency builds confidence and trust?</li> </ul>
<b>Mechanisms</b>	<ul style="list-style-type: none"> <li>▪ Are there adequate mechanisms to enable the regulatory agency to be held accountable by regulated entities, beneficiaries and the government?</li> <li>▪ Does the agency develop its understanding of the needs and preferences of particular audiences and tailor its accountability mechanisms accordingly?</li> <li>▪ Does the agency have appropriate feedback, challenge and appeal mechanisms for those affected by its regulatory activities?</li> <li>▪ Are the agency's accountability mechanisms understood and accessible?</li> <li>▪ Does the agency use the outcomes of accountability, including ways it has changed, to demonstrate the value of engagement?</li> </ul>
<b>Capacity Building</b>	<ul style="list-style-type: none"> <li>▪ Does the regulatory agency have a clear map of those to whom it is accountable?</li> <li>▪ Does the agency recognise a responsibility to build the capability of those it is accountable to? And does it work to make the capability of those who find it most challenging to hold it to account?</li> </ul>

- Can the agency provide evidence that its accountability is effective – including examples of changes to its governance, culture or practices arising from accountability?

The case study below illustrates how the most effective regulatory systems should be able to flex to respond to changing risks, incentivise regulatory compliance and maintain appropriate regulatory independence. A crucial part is how well the funding model addresses the regulatory objectives. The funding model can include funding specific aspects or time-limited projects. For example, the Air Quality Grant Programme supports local authorities to improve air and help them meet their statutory duties under the Environment Act 1995. The Food Standards Agency funds animal feed regulatory enforcement through annual grant allocations to local authorities.<sup>10</sup>

### Supporting Product Safety Enforcement at Borders

When regulatory efforts produce benefits that reach beyond the boundaries of a particular local authority, targeted grants can be employed to guarantee proper compensation for the local authority's role in carrying out these responsibilities on behalf of the broader community. The terms and conditions and the reporting obligations of the grants offer a valuable avenue for government departments or national regulatory bodies to define the scope of regulatory activities, focus their efforts on areas of heightened risk determined through a nationwide assessment, and gain confidence in the execution of regulatory tasks.

The UK's Office for Product Safety and Standards (OPSS) offers financial aid to local authorities near ports and borders to improve product safety enforcement. OPSS provides grant funding to local authorities with ports and borders in their jurisdiction because the benefits of adequate controls at ports and borders go beyond the individual local authority's boundaries.

The Ports and Borders Programme aims to prevent unsafe imports by enhancing surveillance. OPSS provides intelligence to support enforcement activity and tracks monthly performance data, including details of the hazardous products removed from the UK market. This enables the monitoring of performance and informs future risk-based activity targeting. The budget for the grant program in 2022-23 is around £2.3 million.<sup>11</sup>

## 2.4 Culture

Culture is considered within the RDM as a collective understanding and purpose that manifests itself in the visible behaviour of the regulatory agency: 'the way things are done around here'. Culture determines how the regulatory agency will respond to the forces of governance and accountability and supports improvement.

Culture has a powerful influence on any organisation's behaviour and practices and the individuals that make up that organisation. It helps to determine the shape and performance of the organisation and its ability to form functional relationships with others. These factors impact an organisation's credibility and influence public perceptions of it. While culture is vital for all organisations, it demands particular attention from regulatory agencies because, as noted under governance, the

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<sup>10</sup> The [Air Quality Grant Programme](#) helps local authorities make air quality improvements. It has awarded nearly £92 million in funding to various projects since it started in 1997. The [New Feed Delivery Model](#) funds local authorities to conduct enforcement concerned with animal feed.

<sup>11</sup> Page 20, The National Audit Office, 'Lessons learned: How to deliver effective regulation locally', (2023) available from <https://www.nao.org.uk/wp-content/uploads/2023/05/how-to-deliver-effective-regulation-locally-1.pdf>

absence of commercial influences and a regulatory agency's authorisation to exercise the state's coercive power mean that culture plays a crucial role in determining how powers are exercised.

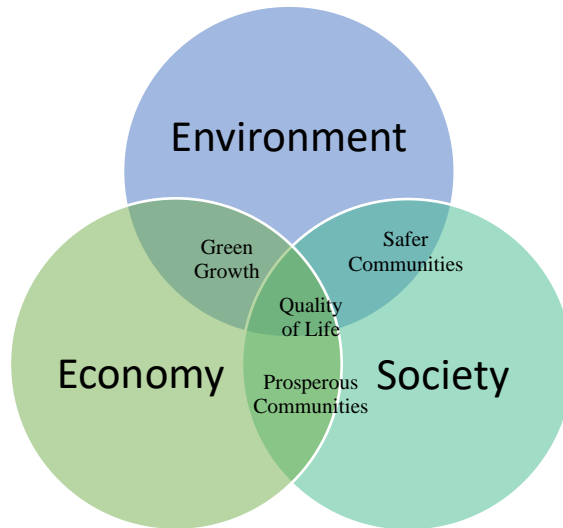
The aspects of culture explored within the RDM are:

1. The nature of the **leadership** of the regulatory agency, including the leadership drive to build an outcome-focused culture.
2. The **values** of the regulatory agency, including their appropriateness to the regulatory task of the agency and the extent to which these are shared values.
3. The **competency** of staff to deliver the purpose of the regulatory agency, including whether knowledge, skills and behaviours are proportionate to the level of discretion.

<b>Culture - Key Lines of Enquiry</b>
<p><b>Leadership</b></p> <ul style="list-style-type: none"> <li>▪ Does the regulatory agency invest in building leadership competence and capability?</li> <li>▪ Do leaders understand their organisation, have its confidence and work effectively with it?</li> <li>▪ Are they modelling appropriate behaviours, values and practices through their words and actions?</li> <li>▪ Are they building a culture that focuses on outcomes?</li> <li>▪ Do they set clear expectations and standards of conduct?</li> </ul>
<p><b>Values</b></p> <ul style="list-style-type: none"> <li>▪ What does the regulatory agency value?</li> <li>▪ Are those values shared throughout the organisation across managerial and operational levels, specialist activities, and commands?</li> <li>▪ Are those values appropriate to the agency's regulatory task? And do they reflect the sort of regulator it aims to be?</li> <li>▪ Are those values communicated, both internally and externally?</li> </ul>
<p><b>Competency</b></p> <ul style="list-style-type: none"> <li>▪ Does initial and continuing training, learning and development ensure the ability of the staff to deliver the purposes of the regulatory agency?</li> <li>▪ Does the assessment and development of competency fully and proportionately address knowledge, skills and behaviours?</li> <li>▪ Is the level of discretion afforded to individuals and decision-making units within the agency proportionate to the competency of the people involved?</li> </ul>

## 2.5 Outcome Measurement

Outcome Measurement is the first of the three practices of the RDM. There is a dynamic relationship between the practices. The regulatory agency needs to identify the outcomes it aims to deliver, identify and prioritise the risks to their results and choose the right interventions to tackle them. It must do this at all levels – from strategic operations to tactical actions. Effective measurement of its progress towards outcomes enables an improvement cycle. **Figure 6** helps regulators to conceptualise their impact at this higher level, focusing on their effect on the environment, the economy and society, not simply against specific regulatory requirements. This is part of moving from ‘Does this inspection improve compliance?’ to ‘How do my interventions protect people and places and support employment?’. Regulators will not necessarily see their work in these terms, but these are the impacts that budget-holders and opinion-formers see as important.



**Figure 6: The strategic impact of the work of regulators**

It should be self-evident that any organisation needs to know what its intended outcomes are and to be able to understand whether it is making progress towards them. Well-communicated results are equally important, internally to give staff a clear sense of purpose and externally to establish a foundation for trust and confidence in the agency. Where the regulatory agency understands and measures the impact of its activities, it can make informed decisions, shifting resource allocation to those activities that contribute effectively and efficiently. However, the indirect nature of the regulatory agency’s contribution, the diversity of contributors, the time lapse between actions and outcomes, and the difficulties in establishing a counterfactual make it challenging to identify the contribution to long-term results. When taken as indicators of success, measures such as the number of inspectors, inspection frequencies, or the number of prosecutions can have a perverse effect.

The aspects of Outcome Measurement explored within the RDM are:

1. **Identifying** appropriate outcomes, from strategic to operational, includes communication of these outcomes and the approach to managing conflicts.
2. The regulatory agency’s understanding of its **contribution** to outcomes resulting from its direct actions and the articulation of this contribution internally and externally.
3. The approach to **measuring** progress towards outcomes includes appropriate indicators, adequate analysis capacity and continuous improvement in data access.

<b>Outcome Measurement - Key Lines of Enquiry</b>
<p><b>Identification</b></p> <ul style="list-style-type: none"> <li>▪ Has the regulatory agency identified appropriate impacts and outcomes, from strategic to operational?</li> <li>▪ Are these communicated and understood, both internally and externally?</li> <li>▪ Do they include short and longer-term societal impacts and broader outcomes, such as confidence and capacity building?</li> <li>▪ How does the agency deal with conflicts (perceived or otherwise) between its outcomes?</li> <li>▪ Is the agency aware of the positive and negative impacts it has on outcomes targeted by other regulatory agencies and vice versa?</li> </ul>
<p><b>Contribution</b></p>

<ul style="list-style-type: none"> <li>▪ How does the regulatory agency understand its (indirect) contribution to impacts and outcomes through the (direct) activity of regulated entities?</li> <li>▪ Does the agency understand how it contributes to impacts and outcomes shared with other regulators and state and non-state actors?</li> <li>▪ What methodologies does the agency use to understand its contribution over time?</li> <li>▪ How well does the agency articulate its contribution, both internally and externally?</li> <li>▪ Does the agency use counterfactuals to assess its contribution and tell the story of its impact?</li> </ul>
<p><b>Measurement</b></p> <ul style="list-style-type: none"> <li>▪ How does the regulatory agency understand its (indirect) contribution to impacts and outcomes through the (direct) activity of regulated entities?</li> <li>▪ Does the agency understand how it contributes to impacts and outcomes shared with other regulators and state and non-state actors?</li> <li>▪ What methodologies does the agency use to understand its contribution over time?</li> <li>▪ How well does the agency articulate its contribution, both internally and externally?</li> <li>▪ Does the agency use counterfactuals to assess its contribution and tell the story of its impact?</li> </ul>

2.6 Risk-Based Prioritisation

Risk-based prioritisation addresses where the regulatory agency chooses to direct its resources. The role of a regulatory agency involves managing risks to regulatory outcomes by reducing their likelihood and/or impact. The role of reducing risk requires the regulatory agency to ensure that its decision-making, at all levels, is based on an informed assessment of risk and that it prioritises based on that assessment. **Figure 7** shows the regulatory risk framework, which enables a regulatory agency to divide regulated entities into four risk bands: High, Upper Medium, Lower Medium and Low.

**Likelihood of non-compliance**

	Very low	Low	Medium	High	Very high
High	Lower Medium	Upper Medium	Upper Medium	High	High
Upper medium	Lower Medium	Lower Medium	Upper Medium	Upper Medium	High
Lower medium	Low	Lower Medium	Lower Medium	Upper Medium	Upper Medium
Low	Low	Low	Lower Medium	Lower Medium	Upper Medium

Figure 7: Regulatory risk framework

Regulatory agencies exist because there is a risk of harm that would only be appropriately managed with their intervention. Over time, the purpose of the regulatory agency is to manage that risk by reducing the likelihood or impact of harm (or both). In making decisions about resource allocation, the regulatory agency must assess and compare different threats and potential threats to the regulatory outcomes it is working towards. The concept of regulatory risk provides a means of evaluating challenges to desired regulatory results. It provides a structured way of thinking about relative impacts, positive or negative and comparing them so that the regulatory agency can direct its efforts proportionately to the risk. Risk can be conceptualised as 'the currency of regulation'.

The aspects of risk-based prioritisation explored within the RDM are:

1. The importance of effectively **identifying and assessing** risks to the regulatory agency's outcomes at all levels, from strategic to operational.
2. The need to use all available **data, information and intelligence** to identify and assess risk, a proactive approach to closing data gaps and effective data sharing.
3. The approach to **using risk**, including the risk frameworks used, the link between risk and prioritisation and the transparency of the risk-based prioritisation approach.

<b>Risk-Based Prioritisation - Key Lines of Enquiry</b>
<p><b>Identification and Assessment</b></p> <ul style="list-style-type: none"> <li>▪ Does the regulatory agency understand and articulate risks to its outcomes at strategic and operational levels?</li> <li>▪ Does the agency effectively identify and assess risk?</li> <li>▪ Does the agency understand its risk context in terms of shape, colour and routes to risk, as well as the level of risk?</li> <li>▪ Does the agency have access to and use sufficient resources for horizon scanning and understanding changes in risk?</li> <li>▪ Does the agency recognise its role in shaping perceptions of risk?</li> </ul>
<p><b>Data, Information and Intelligence</b></p> <ul style="list-style-type: none"> <li>▪ Is the regulatory agency's risk assessment (regarding hazard and the likelihood of harm) informed by effectively using all available data?</li> <li>▪ Does the agency have access to and use sufficient resources for risk analysis?</li> <li>▪ Does the agency take a proactive approach to identify and closing data gaps?</li> <li>▪ Does the agency share data with other regulators effectively?</li> </ul>
<p><b>Using risk</b></p> <ul style="list-style-type: none"> <li>▪ Does the regulatory agency make use of risk frameworks? Are these developed in consultation with others?</li> <li>▪ Does the agency prioritise and de-prioritise based on risk at all levels?</li> <li>▪ Does the agency's use of risk underpin a culture of being intelligence-led?</li> <li>▪ Does the agency maintain a 'watching brief' on low risk?</li> <li>▪ Is the risk-based prioritisation process transparent to regulated entities and beneficiaries?</li> <li>▪ Does the agency's use of risk assessment allow regulated entities to engage with their risk score, earning recognition for their compliance activities?</li> </ul>

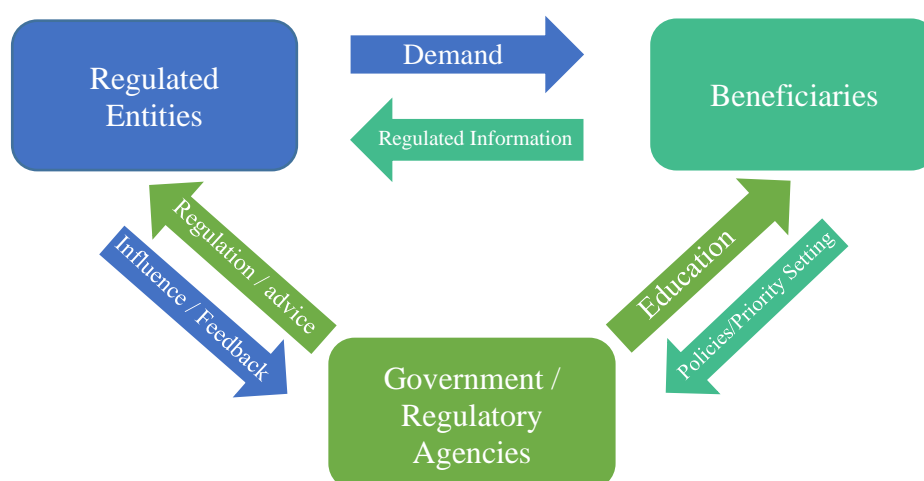


## 2.7 Intervention Choices

The question of how a regulatory agency, being clear on its outcomes and having decided where to direct its resources, should best use them is considered within the RDM in terms of its Intervention Choices. The task of regulatory agencies, while often expressed in enforcement, controlling or mitigating risk or ensuring compliance with regulation, is fundamentally about changing the behaviour of regulated entities. Therefore, the question for a regulatory agency is what will most effectively provide the desired behaviour amongst those it regulates.

A wide range of interventions is available to most regulatory agencies that can be used in conjunction with or as alternatives to a standard licence, inspection or investigation-based approaches. These include initiatives to raise awareness and understanding of requirements amongst those they regulate, oversight of industry compliance initiatives, and initiatives to empower the beneficiaries of regulation, particularly those most at risk. Where a regulatory agency uses a narrow range of interventions, it is less likely to be effective. Comparisons and choices between interventions should be based on evidence of the effectiveness of different intervention strategies – whether the regulator or other regulatory agencies have previously used these.

Regulatory agencies have traditionally focused on their interactions with regulated entities. However, there is increasing recognition that whilst direct intervention by the regulatory agency may be the most appropriate tool in some circumstances, this is only sometimes the case. Regulatory agencies can use the various relationships within the regulatory landscape, as shown in **Figure 8**, whether in addition to or instead of more traditional interventions, to drive regulatory outcomes.



**Figure 8: Actors in the regulatory system**

The aspects of intervention choice explored within the RDM are:

1. The **range and shape** of interventions available to a regulatory agency and its capability to choose interventions effectively.
2. The need to focus on **building compliance** of regulated entities, including understanding motivations and capability and assessing the impact of interventions.
3. **Using sanctions** to drive appropriate outcomes, including monitoring to assess their impact.

## Intervention Choices - Key Lines of Enquiry

### Range and Shape

- Does the regulatory agency respond appropriately to the shape of its regulatory environment?
- Does the agency have the capability to choose interventions effectively?
- Does the agency use all of the interventions made available to it in legislation, including its discretionary powers?
- Does the agency use, as appropriate, all other intervention options available (including not intervening)?
- Does the agency have a practical methodology for understanding when and how beneficiaries and other actors can be equipped to intervene to improve outcomes?
- Does the agency work effectively with partners in its deployment of intervention choices?

### Building Compliance

- Can the regulatory agency understand and assess the impact of alternative intervention choices?
- Does the agency assess the characteristics of the entities it regulates in ways that enable it to understand which intervention choice will be most effective (responsive regulation)?
- Does the agency deploy this thinking to understand the sector and, where appropriate, individual businesses regarding awareness, motivation and capability?
- Does the agency respond effectively to the maturity of the regulatory requirements it enforces and the sectors it works with?
- Does the agency assess the impact of its interventions and modify its behaviour accordingly?

### Use of Sanctions

- Does the regulatory agency have access to an adequate range of sanctions?
- Does the agency use the sanctions available to it to drive appropriate outcomes?
- Does the agency monitor the use of sanctions, including those issued by the agency and through courts and other means, to assess their impact?

The RDM enables a review of how effectively they are implementing regulation. To assess to what extent, they have the right conditions to operate and how well they are doing the things they are responsible for.

## 3 Basing Regulation and Regulatory Action on Scientific Evidence: The Outcome-Based Collaboration Model

### 3.1 The Scientific Evidence Base

There is extensive scientific research on how people behave, why and when they observe or break the rules, and what incentives and stimuli support compliance and good behaviour or conversely undermine those outcomes. Different streams of research exist in human behaviour and psychology, sociology and how people behave in groups or organisations, the causes of disasters, the effectiveness of various control and enforcement regimes and tools, how to run influential corporations, and the relevance of ethics and cultures. This research forms a coherent, consistent and extensive knowledge about how best to 'control' others' behaviour and reduce future risk. Science shows that some popular concepts about human motivation and how to regulate others need to be corrected.

Some of the conclusions are as follows:<sup>12</sup>

- a. People are not objective, amoral, rational calculators of traditional economic theory or can constantly control their behaviour as responsible, rational beings imagined by conventional philosophy.
- b. There are many reasons why people break the rules, ranging across a spectrum from the dishonest/criminal through the well-intentioned but distracted, incompetent, lack of resources, or just an accident.
- c. Deterrence theory has little impact in avoiding errors or reducing future risks.
- d. There are many other ways to avoid errors and reduce future risks.
- e. Good people usually respond if supported to improve their competence, performance awareness, etc.
- f. There is much psychology (supporting rather than undermining people's intrinsic motivation) and research on how 'enforcement' works (or doesn't) that addresses this. In particular, interactions that support people's need to feel competent, autonomous and related to others help internal motivation and are effective, whereas diminishing those perceptions has the converse effect.<sup>13</sup>
- g. Where people fear that they or their group may be blamed, this prevents them from sharing information, and therefore, lessons on how to behave differently and improve performance are lost.

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<sup>12</sup> Overview books are Hodges, C. (2015). *Law and Corporate Behaviour*. Bloomsbury Publishing.; Blanc, F (2018). *From Chasing Violations to Managing Risks: Origins, Challenges and Evolutions in Regulatory Inspections*, Edward Elgar Publishing.; Feldman, Y. (2018) *The Law of Good People: Challenging States' Ability to Regulate Human Behavior*. Cambridge University Press.; van Rooij, B. and Fine, A. (2021). *The Behavioral Code*. Beacon Press. Boston; Tyler, T.R. (2022). *Advanced Introduction to Law and Psychology*. Edward Elgar Publishing.

<sup>13</sup> Ryan, R.M. and Deci, E.L. (2017). *Self-Determination Theory: Basic Psychological Needs in Motivation, Development, and Wellness*. Guilford Press.

### Conclusions for regulatory action

1. Managers and regulators 'enforcing' rules should differentiate between those who are well-intentioned and those who are not. These two groups must be managed differently.
2. For the group who are not well-intentioned, the need to ensure protection from their doing harm to others may need firm enforcement measures. Groups and societies need to take practical steps to protect themselves and their members from damage caused by those who are not ethically self-motivated co-operators. Here, enforcement using 'hard' tools is fully valid. For example, civil aviation authorities can resort to removing or limiting operating licences. Criminal courts can remove people's liberty. These measures demonstrate to others that the law is being upheld and that the same rules apply equally to all, thereby supporting feelings of self-motivation in other group members to follow the rules. However, this is positive reinforcement rather than fear-induced deterrence.
3. However, using complex 'enforcement' tools on those who believe they are well-intentioned can reduce the desire to comply and actual compliance. Focusing solely on 'enforcement', including those who think of themselves as good citizens, also turns out to be ineffective and needs to be revised to maintain adherence to the norms and rules.
4. For the well-intentioned group, usually comprising the majority of well-meaning people, the basis of the approach rests on Self-Determination Theory (SDT),<sup>14</sup> taking steps to address issues of improvements in competence, focus, behaviour, culture and systems by supporting feelings of competence, autonomy and relatedness, and not undermining those feelings.
5. Powerful self-motivation forces operate automatically in most humans to maintain their senses of behaving ethically and of self-worth and reputation, satisfying their need to belong to a social or work group, including an organisation or nation. If such people feel that they are (all) treated relatively and subject to fair and fairly made. In a culture of psychological safety and cooperation, applied norms and rules will be strongly motivated to share information on where things have gone wrong and contribute to making changes to improve things. A regime perceived as punishment or controlling through fear will not be constructive for most people. It will undermine and ultimately destroy senses of competence, autonomy, relatedness, fairness and cooperation. Hence, support and intervention are required to increase competence, autonomy and improvement. Concepts such as punishment, deterrence and enforcement will not be helpful.

#### 3.1.1 Risk Factors

The analysis of the causes of breaking the rules and of disasters indicates that the following are major risk factors for breach of rules and creation of harm:

- a. Lack of competence and capability.
- b. Lack of resources and capacity.
- c. Psychological factors, e.g., focus, distraction, focus on specific targets, crowding out (e.g., focus or emphasis on particular goals at the expense of a broader balanced perspective; incentivisation to meet specific targets, especially if income, status or job is conditional on these), influenced by internal procedures and culture.
- d. Under-estimation of risk, recklessness, over-confidence.
- e. Absence of consistency and systems, and unthinkingly following a system without critically considering it or a potential risk.

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<sup>14</sup> Ryan, R.M., and Deci, E.L. (2017). *Self-Determination Theory: Basic Psychological Needs in Motivation, Development, and Wellness*. Guilford Press.

- f. System design and operation: interaction of multiple parts or people without triggering a warning of impending risk.
- g. Organisational culture(s) that fail to support adequate or critical thinking, or ethical behaviour that focuses on achieving the full range of desired outcomes, or the ability to listen to or act on evidence of problems.

### 3.1.2 Evidence on the Need for Legitimacy and Fairness of Regulatory Behaviour, Processes and Rules

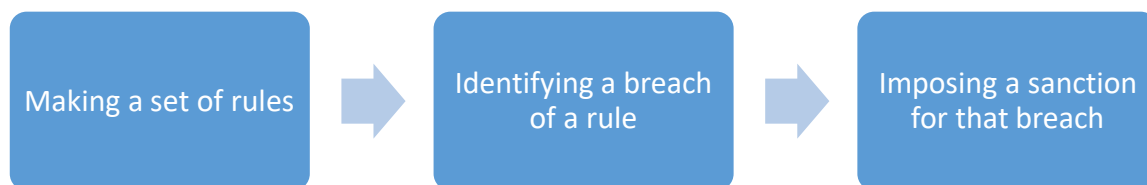
Extensive research has illuminated the factors that affect whether people feel motivated to obey social or legal rules. The principal elements are:<sup>15</sup>

- a. The rules are made through a fair *process*, where people feel they have been involved or a possibility for voice and input.
- b. The *rule's substance* is considered fair by the individual and most of the community, even if individuals disagree.
- c. The rule accords with their sense of *values*, namely the values of the individual, the particular community, social group, or organisation.
- d. The rule is *applied* fairly by/to all.
- e. Most people are *observing* the rule.

#### 3.1.2.1 Implications for Updating the Relevant Concepts and Language

The scientific evidence shows that punishment, enforcement, and deterrence concepts must be updated (often ineffective) in most situations. Enforcement, intervention, or requirements are relevant when delivering adequate protection from unacceptable harm. However, it is essential to differentiate between those with ethical intentions and those without (in effect, criminals) and use different tools to respond to those two broad groups. In simple terms, vigorous enforcement is relevant for the latter, whereas support and intervention are relevant for the former.

The traditional regulation model involves a three-staged process, as outlined in **Figure 9**.



**Figure 9: Traditional model of regulation**

However, this linear, responsive approach has significant drawbacks. First, the sanction occurs *after* a breach or harm has happened, so it is not directly preventative. Second, it focuses on complying with a rule rather than aiming to *improve performance*, whether up to a required standard or above. Third, it typically focuses on blaming an individual or organisation rather than asking whether a system might be the root cause and whether any human in the same situation would act similarly.

For these reasons, high-risk safety regulators (such as aviation and nuclear safety) operate Performance-Based Regulation aimed at constant vigilance and improvement in an ‘open and just culture’ involving psychological safety. Various other effective regulators (e.g., under the RDM) discuss identifying the right ‘intervention choice’, in which traditional enforcement tools are only one (extreme) option.

<sup>15</sup> Tyler, T.R. (2022). *Advanced Introduction to Law and Psychology*. Edward Elgar Publishing.

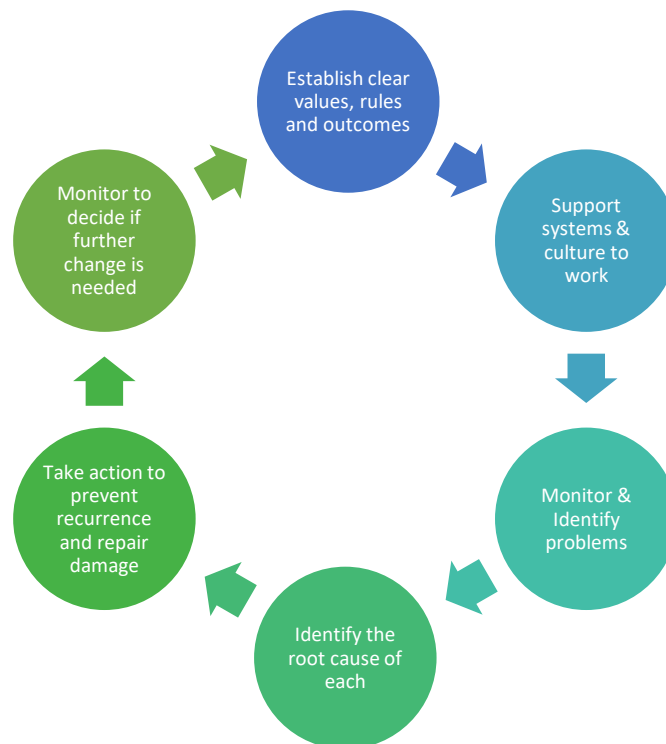
A fundamental shift is occurring across many sectors from a regulatory model that is a rule-breach-enforcement mode to one of values-objective-outcomes-data-feedback-fixing problems-improving performance. The latter method exists under a system that delivers the following functions:

1. Identifies where people need improved competence, resources, focus, and
2. Provides the proper support, reserving protective enforcement as a last or urgent resort but
3. Maintain the protection of society and markets by using tough enforcement measures on those who deliberately break the rules and harm others. This requires the segmentation of people/organisations based on the extent to which their intentions are ethical and their demonstrated competence.

### 3.1.3 The Problem-Solving Model

The ideal will follow the circular problem-solving model illustrated in **Figure 10**, involving cooperating in the performance of these functions:

- a. Establishing clear values, rules and outcomes.
- b. Establishing the systems, procedures and cultures that will operate to achieve, and not impede, achievement of the desired outcomes by values-based means and behaviours.
- c. Monitoring to ensure that the system and behaviours are working well and that outcomes and improvements in performance are being achieved. This will involve identifying problems, risks, harm, inadequate performance, and non-compliance with standards.
- d. Identification of root causes of problems, harms and what steps need to be taken.
- e. Taking action to stop unacceptable harm or behaviour, identify steps to address the risk to an acceptable level, and ensure that those steps are implemented. Failure to implement and to take steps to change culture is frequently overlooked here.
- f. Monitoring to see if any further changes are needed and implementing them.



**Figure 10: The Problem-Solving Cycle**

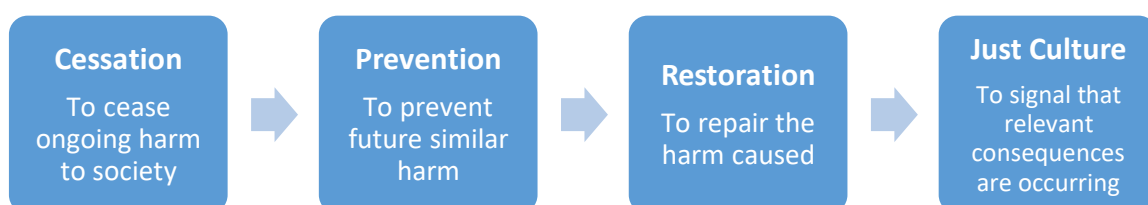
## 3.2 The Principles of Regulatory Intervention

*The purpose of, and justification for, regulation and regulatory action* in modern states is to deliver **protection** from harm. This applies to protecting safety and health, fair markets and innovation, the environment and the planet, and sound administration and government.

The following principles should apply to regulatory intervention by a public authority:

- a. Intervention by a State to *protect* itself and its citizens must be justified based on protecting society and reducing future risk rather than as punishment or deterrence.
- b. Society and the intervention must follow ethical principles.
- c. Force can only legitimately be used by a duly constituted legitimate authority to protect the ethical values of society.
- d. Intervention must be proportionate and be under a duly constituted process following the law.
- e. It is illegitimate as a matter of constitutional and human rights principles for a modern ethical State to rule citizens through fear. Therefore, force may not be legitimately used to inflict harm or punishment on others. The purpose and effect of using power must be to provide protection, not punish.
- f. Any measures taken must be proportionate to the need to protect society.
- g. Any measures taken must be based on the best available scientific evidence of their effectiveness in reducing the incidence of future risk of unacceptable harm and in achieving legitimate outcomes for society.
- h. Measures should also be taken to make good any harm caused.
- i. It should be expected that citizens and businesses should intend to act ethically in contributing to a fair society and world. Still, they should demonstrate this, behave accordingly, and be trustworthy.
- j. A practical approach is to encourage all actors and interactions to be based on trust. Trust is based on evidence of how people behave. Humans automatically assess evidence based on whether people behave well or not (i.e., against ethical values and norms). Hence, for maximum effectiveness, people should produce evidence that they intend to act ethically (including when things go wrong) to create and sustain trust and social capital relationships.

The objectives of the intervention, covering the three dimensions of time (present, past and future), are set out in **Figure 11**.



**Figure 11: The Objectives of a Regulatory Intervention**

How protection may be delivered varies, primarily differentiated by the motivations, competence, resources, attention, and cultures of the proximate actors who cause harm and the systems in which they operate. Forward-looking activity is about *prevention*.<sup>16</sup>

<b>How Protection May be Delivered</b>
<p><b>For actors:</b></p> <ul style="list-style-type: none"><li>a. The goal of protection may sometimes need decisive action (classic enforcement in style), such as removal or qualification of licences to sell or operate some or all products, services, activities or markets.</li><li>b. This is particularly so where the motivation of the infringer is to operate intentionally to make gains illegally, without due regard to causing harm to others.</li><li>c. Well-intentioned actors should be encouraged to improve their performance, competence, behaviour or activities and follow society's ethical rules.</li><li>d. Where relevant, intervention tools that support ethical behaviour (compliance with the norms and rules) and improvements in competence and performance, inform, educate, improve, and reduce risk should be used.</li></ul>
<p><b>For society:</b></p> <ul style="list-style-type: none"><li>a. An essential outcome in every case is removing any gains resulting from illegal behaviour and redressing any harm caused.</li><li>b. All actions should be transparent and fair so that the general population will perceive that others observe the rules, and that appropriate action is taken against those who (deliberately or recklessly, and maybe carelessly) break the rules so that society is protected, the rules are upheld, the cohesive fabric of the society is maintained and consistent, harm is repaired, and that lessons are learned and applied so that performance improves, and risk is reduced. E.g., improvement in competence and performance, plus redress?</li><li>c. All regulatory action should follow this policy and with detailed policies that are appropriate to the particular circumstances of individual regulatory regimes and situations.</li></ul>

Regulatory enforcement should comply with the constitutional principles of the fair and legal process and be appropriate and proportionate in style and manner.

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<sup>16</sup> Better Regulation Delivery Office. (2016). *Regulation and Growth*.



### 3.3 Policy on Regulatory Action: Restating the Objectives of Enforcement, Sanctioning and Intervention

The essential functions that people wish to see as occurring after the occurrence of harm or breach of rules are:

- a. *Identifying* harm and risk (and non-compliance).
- b. *Stopping* ongoing harm and risk. This follows from identifying a problem and also involves analysing the root cause of the issue.
- c. They are repairing the harm caused. Redress is paid, and all illicit gains are removed from the perpetrator.
- d. *Protection and risk reduction*. Making changes so that the same harm does not occur again and/or the future risk is reduced. The nature of the relevant change directly (e.g., compliance notice) or indirectly (penalty acts as an incentive to comply in future)

Based on retrospective and prospective viewpoints, the aims are:

Looking forward:

- Aim to deliver protection of people from risk and harm.
- Encourage the commitment to practical actions by the offender to provide protection and compliance in future.
- Aim to eliminate any financial gain or benefit from non-compliance.
- Ensure that requirements and interventions imposed on offenders are proportionate to non-compliance, harm, and risk.
- Aim to affect behaviour, culture, and systems to reduce risk to the society by responding effectively and proportionately, based on the agreed ethical principles of protection, intervention, science, information and understanding, differentiating between actors who have had a role in the occurrence, based on the evidence of their commitment to the ethical regulatory principles.

Looking backwards:

- Aim to ensure the commitment of and practical actions by the offender to rectify the harm caused.
- Ensure that any harm and loss caused by the non-compliance is rectified and remedied.
- Ensure that any financial gain or benefit from non-compliance is removed.

A simple slogan might describe the primary outcomes people want to see as STOP, FIX, REDRESS.

Regulatory action (i.e., deciding how to respond on the spectrum of enforcement and intervention) should consider the following considerations relevant to offenders:

- Levels of competence or incompetence pertinent to activities and risk.
- Motivation and actions at the time of non-compliance. For example, did they
  - Intend to do the right thing? Was the action a deliberate breach, blindness, recklessness, lack of focus on relevant risk, negligence, or carelessness? To what extent can these supposed states of mind be accurately identified by others after the event? This is especially relevant in the case of organisations or groups of humans.

- Focus on other worthy or unethical goals rather than on a causative factor or consideration that caused the harm/breach.
- Up to now, motivation and actions after the breach or occurrence of harm. For example, did they swiftly identify and stop the problem, involve relevant others such as experts or the regulator, and act spontaneously to repair damage and to make changes to reduce risk? Or did they cover up the problem, obfuscate, frustrate, or mislead the regulator or relevant others?

**Enforcement undertakings (EUs) - The UK Environment Agency’s Stop, Fix, Redress approach.**

An EU is a voluntary offer made by an offender to:

- put right the effects of their offending
- put right the impact on third parties
- make sure the offence cannot happen again

If the offer is accepted, it becomes a legally binding agreement between the Environment Agency and the business or person who makes the offer. The Environment Agency only consider taking an EU for cases where:

- it is not in the public interest to prosecute
- the offer itself addresses the cause and effect of the offending
- the offer protects, restores or enhances the natural capital of England

**LIL Packaging Limited (reference 838)**

The offence was operating without or other than by an environmental permit (water discharge activity) – Regulation 38(1). It relates to the unauthorised discharge of printing ink and pollution of a River Ouse, Huntingdon, Cambridgeshire tributary in April 2020.

This was a reactive offer. The actions the offeror has taken or will take are to:

- update its induction process and training
- provide training for existing staff and install new signage
- install a waste ink treatment system
- reimburse clean-up costs
- cover the Environment Agency’s costs

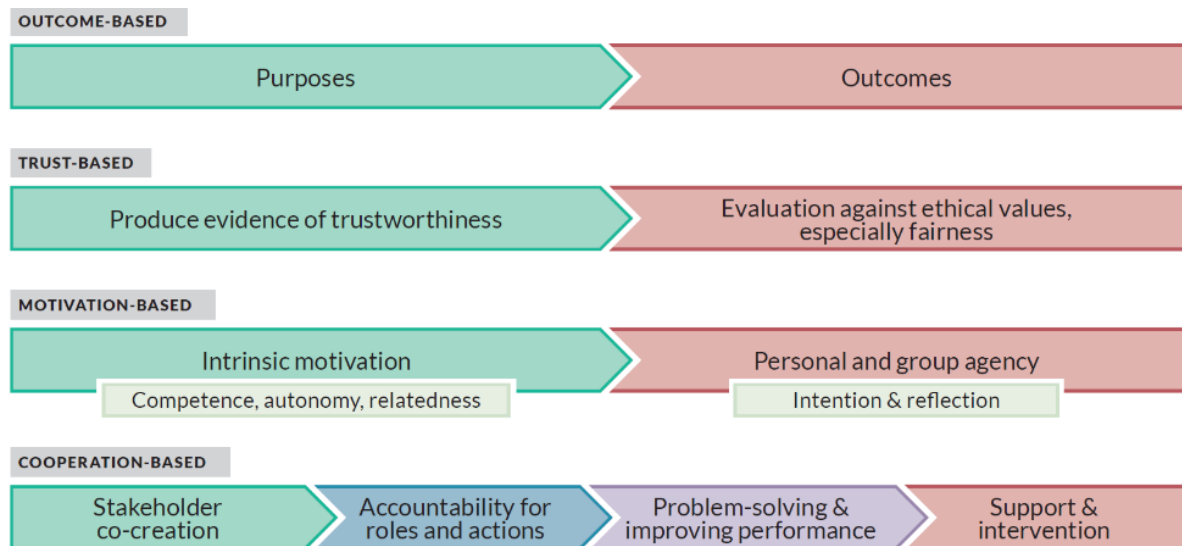
They will contribute £20,000 to the Little Ouse Headwaters Project.

Accepted enforcement undertakings are published on the Government website.

[Enforcement undertakings accepted by the Environment Agency: updates for 1 June 2022 to 31 May 2023 - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/collections/enforcement-undertakings-accepted-by-the-environment-agency-updates-for-1-june-2022-to-31-may-2023)

### 3.4 Outcome-Based Cooperative Regulation

Based on the evidence that humans achieve more when they collaborate and that approaches that build trust and involve behaviour based on SDT principles support cooperation, the ideal is to build relationships, behaviour and cultures in which those who demonstrate that they are trustworthy are engaged as equal stakeholders in achieving agreed on everyday purposes, objectives and outcomes. The scientific evidence set out above formed the basis of a model called **Outcome-Based Cooperation Theory** ©,<sup>17</sup> as shown in **Figure 12**.



**Figure 12: Outcome-Based Collaboration Theory**

Cooperation can be enhanced by the following means:

1. Agreement on Purposes and Outcomes and
2. A Culture of Trustworthiness based on evidence, values, and ethics.

#### 3.4.1 Agreement on Purposes and Outcomes.

To collaborate, we need to know what we are cooperating about. What are we trying to do and achieve? What outcomes do we intend to deliver? Which outcomes are good, and which ones are harmful? We can then monitor results and see whether we deliver good or bad outcomes. We can see if we are improving our performance or not.

However, we need to agree on our everyday purposes and priorities. Since there are many purposes, some conflict with others, we must discuss, agree and rank them. We might not be able to achieve all objectives simultaneously, so sequencing is critical.

For example, corporations need to produce profits, but society needs protection from harm: the classic regulatory conflict. Corporations, however, can pursue many more purposes, such as employment and various social, environmental, community, and national goals. This reality is reflected in the shift in emphasis in corporate management and regulation from maximising shareholder value as the sole purpose of corporations to the pursuit of Environmental, Social and Governance (ESG) goals and conscious, stakeholder capitalism.

<sup>17</sup> Hodges, C. (2022). *Outcome-Based Cooperation: In Communities, Organisations, Regulation, and Dispute Resolution*. Hart.

It will be more effective to agree on achieving all these purposes in advance rather than expect companies and regulators to work out the answers once a conflict arises. Admittedly, it is far easier for regulators to measure their outputs—such as the number of statements or rules issued or the number of inspections or fines imposed—than to demonstrate outcomes such as safe streets, internet, or investments. However, it is the outcomes that matter. Stating them clearly will help.

Whether achieving improved outcomes will be more accessible or challenging depends on various personal, social, and public factors that facilitate or impede cooperation. For example, the Nordic states and New Zealand benefit from high social capital, while numerous nations are held back by corruption and a need for coordination mechanisms. Similarly, attempts to ‘control’ employees are problematic.

The ideal, though, is achievable. It primarily exists in high-risk safety systems, such as aviation safety.

#### **Aviation Safety**

The system was devised in the 1980s and moved away from a model based solely on rules and enforcement to a performance-based ‘open and just’ culture in which blame is almost removed in order to get everyone to collaborate across a network of all public and private organisations and actors. We all have confidence and trust when getting on a plane that we will get off at the other end. Considering the technical complexities and the number of people involved, this is remarkable.

This is what they call an open and just culture. In an open culture, they share all information all the time on the basis of trust; and in a just culture, there are always consequences when a problem is identified.

The Boeing 737 MAX disasters demonstrated what happens when responsibility is delegated without justified trust and a commercial organisation pursues only a profit goal, corrupting the culture.<sup>18</sup> Other example includes Volkswagen’s ‘dieselgate’.<sup>19</sup>

#### 3.4.2 A Culture of Trustworthiness based on evidence, values, and ethics.

Cooperation is based on trust. Trust is the mental mechanism that enables people to plan and act in the face of uncertainty. Predicting the future is impossible, but people can have confidence that things will work well and trust that people will behave as expected.

All human systems and relationships are based on *trust*. Nevertheless, people often [say](#) they do not trust politicians, companies, or partners today. We should not be surprised if conflict and under-achievement are the consequence.

Trust is based on *evidence*. The best evidence builds up over time, forming a consistent and coherent whole about whether someone can be trusted. Much evidence in investment, markets, and regulation is familiar, including auditing results and systems that control activities against agreed standards. We have recently realised that evidence of behaviours and organisational cultures is also essential, even if challenging to produce.

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<sup>18</sup> U.S. Department of Transportation, Office of Inspector General. (2021). *Weaknesses in FAA’s Certification and Delegation Processes Hindered Its Oversight of the 737 MAX 8*. Report No. AV2021020, 23 February 2021.

<https://www.oig.dot.gov/sites/default/files/FAA%20Certification%20of%20737%20MAX%20Boeing%20II%20Final%20Report%5E2-23-2021.pdf#page=41>

<sup>19</sup> Atiyeh, C. (2019). "Everything You Need to Know about the VW Diesel-Emissions Scandal." *Car and Driver*, 4 December 2019, <https://www.caranddriver.com/news/a15339250/everything-you-need-to-know-about-the-vw-diesel-emissions-scandal/>

Humans evaluate evidence of behaviour, official standards, and rules against an inherent set of *ethical values*. People’s brains are wired to know the difference between right and wrong. Nevertheless, people also possess heuristics and biases. They can maintain self-worth by tricking themselves into believing that what they do is right—cognitive dissonance. This ability means being careful and open to scrutiny; the challenge is crucial.

The trick is to turn things around: **Can an organisation prove why it should be trusted by staff, investors, customers, and society?** An organisation that deserves trust consistently is *trustworthy*. Creating a community of trustworthy organisations will support collaboration and more remarkable achievement of good outcomes.

Humans perform better when their *intrinsic motivation* is high. All good managers—and employees—know this. Supporting others’ autonomy, competence, and relatedness works; undermining these qualities impedes performance.

Trying to create incentives and rewards in human terms works better than in terms of financial targets—and it also reduces the risk of bad outcomes. Similarly, setting universal human, social, and environmental goals—such as achieving prosperity and protection—will generate broader involvement and increased trust.

### 3.4.3 The Core Elements of Outcome-Based Cooperative Regulation.

The core model of outcome-based cooperation in regulation involves *six core elements*.

1. All stakeholders agree on purposes, outcomes, evidence metrics, and systems.
2. They agree on expectations for how those who wish to be trusted should behave and set out this agreement in a code.
3. All actors who wish to join the ‘trust community’ and ‘regulatory trust track’ produce evidence that they are trustworthy. The type of evidence will evolve and be proportionate to the business and risk.
4. Those actors who do not wish to produce evidence of trustworthiness continue to be regulated under traditional rules and enforcement but without the benefits of having a trusted reputation, including benefits of regulatory sandboxing, such as procurement, commercial, employment, and investment advantages and a reduction in regulatory burden.
5. The trusted parties collaborate in a trusted and respectful environment, identifying and fixing problems, achieving desired outcomes, and increasing performance.
6. All parties help to identify harms and risks quickly and take action to deliver protection.

The essential elements of an outcome-based cooperative regulation typically involve three core players. The first is a stakeholder council that oversees the entire system’s operation and mode of operation. The stakeholder council ensures that the system operates well and has no gaps. It also sets the primary code of behaviour.

The second player—the regulator—represents the state and works to protect society and markets overall. It oversees the operational aspects of the system. It may be empowered to make the code mandatory to refer complaints to an ombudsperson. It also enforces the legal rules that act as the boundary of society’s requirements, any breach of which may trigger enforcement action. However, it differentiates between deliberate and reckless behaviour or violations—which may trigger enforcement—and those that occur by well-intentioned actors who take an ethical approach to preventing, identifying, rectifying, and learning from risk and harm—which would usually trigger cooperative support and intervention.

The third and final player in an outcome-based cooperative regulatory system will be an ombudsman, an independent source of trusted information, advice, early resolution of problems and disputes, and decisions applying the code, including referring points of law to a judge. The ombudsman is crucial in providing information and communication between parties and mediation. It works to aggregate data from all inquiries and disputes and then feeds the learning back for appropriate action by companies, regulators, consumers, and others.

Many of these elements operate well in the United Kingdom and other markets. They draw together developments in regulation and enforcement, as well as in dispute resolution and the use of online systems and artificial intelligence. They build on learning about why problems occur in organisations and businesses—and how to avoid them. Today, ground-breaking examples of the complete model of outcome-based cooperation are being considered in areas as diverse as financial services, energy and climate change, water, property and housing, biomedicine, and medical devices.

Ultimately, society must collaborate more to solve the world's complex problems. Orienting regulation more toward cooperation is one crucial step in a much-needed direction.