

# A good regulation guide

How to reform the UK's regulatory  
landscape



# Content

Foreword	Page 3
Executive summary	Page 5
Regulatory reform: a brief history	Page 7
Is regulation supporting growth ambitions?	Page 11
Thematic reforms	Page 23
Strategic regulatory reforms	Page 29
Regulation as a driver of industrial strategy	Page 34
Closing reflections: The vital role of regulatory reform in strengthening the business community	Page 45
References	Page 46
Appendices	Page 47

## Foreword

There is a fierce urgency in the need to get the UK economy growing at a rate which will make a meaningful difference to our nation's and our fellow-citizens' prosperity. Not just for the sake of decimals in data sets, or pounds in bank accounts, but for society and the delivery of world class public services.

In the 20 years before the 2008 Global Financial Crisis, our growth rate was broadly similar to that of the United States; since then it has been less than half. Our GDP per capita is now less than the poorest state in the United States, which is Mississippi, and it shows in the quality of our infrastructure and our public services.

We are going to have to deploy every tool in the policy toolbox to get us back onto a path of growing prosperity and national economic revival. One of the most important tools in a modern economy is regulation, which affects every market and every business and every citizen. The UK used to have a justified global reputation for thoughtful innovation in regulation and in the years before the Global Financial Crisis much of our growth was driven by changes to regulation, particularly in Financial Services and Utilities.

But somewhere along the way, we have lost a sense of proportionality and the recognition that the purpose of regulation is not to remove all risk from endeavour nor to protect every citizen from every risk that might arise. And as a consequence, in many areas of life we find ourselves tangled in knots of rules and regulators which weigh down on businesses' ability to invest and grow.

So, we need to set about regulatory reform. 'Reform' does not mean eradication of rules, in fact far from it. The UK's calling card for investment has long centred on predictability, institutional excellence and fairness. Business does not want this eroded, but creating the intellectual, financial, and experimental space for the private sector to invest and grow needs a new way of thinking. And businesses recognise that good regulation is a competitive advantage both within our UK market, and in attracting new investment into our economy.

To its credit, the UK Government have started this conversation and have begun to act. The CBI and its members have concurrently begun to articulate their role in delivering this fresh regulatory landscape. One which drives our international competitiveness and embeds both innovation *and* compliance.

For industry, there are **four** domestic priorities for policy co-design with government as we look ahead. Firstly, ensuring the UK's future regulatory regime is **outcomes focused**, and principles based. Secondly, placing **standards integration** at its heart. Thirdly, embedding a more **robust data-driven baseline** within the future regime. Fourth, cementing the strength of the **Industrial Strategy** through clear regulatory changes.

Changes to UK regulations should not be made in isolation. Over the next year, the UK has a key opportunity to address both trade and regulatory barriers with the EU, as part of the EU-UK reset and the formal review of the EU-UK Trade and Cooperation Agreement. It will be crucial to identify areas for enhanced regulatory cooperation and alignment, while also understanding where divergence serves the UK's strategic interests.

In a world where UK industry spends billions on compliance, and works with hundreds of regulatory bodies, reform will inevitably take time. But with a starting point and consensus across Business and Government that regulation must support, not hinder, growth, a recognition that we need to think more openly about risk appetite, and a fair set of red lines for consumer protection, rapid progress is possible.

An ambitious Government and an economy-wide commitment to reform of regulation presents a window of opportunity which opens infrequently. We must not let it close again without making real progress.

**Rupert Soames OBE**  
Chair, CBI



## Executive summary

Despite multiple attempts at reform, the UK's regulatory framework remains suboptimal, failing to drive the economic growth the country needs. In recent months, the government has recognised this challenge, outlining an ambitious set of reforms in its *New approach to ensure regulators and regulation support growth* policy paper.<sup>1</sup> However, to remain competitive and attract investment and innovation, the UK's regulatory framework must remain responsive to changing economic conditions.

While practical reforms are essential to address immediate barriers to growth, a broader, system-wide approach is equally crucial. Regulatory reform must be applied holistically, aligning with the ambitions set out in the UK's industrial strategy to create a more dynamic and future-ready regulatory environment.

This guide presents an industry-led perspective, offering constructive solutions to some of the most pressing economic challenges of our time. By adopting a smarter, more strategic approach to regulation, the UK can unlock greater investment, innovation, and long-term prosperity.

Founded 60 years ago and representing some of the biggest names in business, household brands and globally traded corporations that employ people in all sectors and across every region and nation of the UK, the CBI is the voice of business. The CBI represents 850 members who themselves comprise 1,100 separate registered companies and 150,000 trade association members. Throughout 2024-25 the CBI has engaged with members through the Regulatory Reform Taskforce, a cross-sector group representing heavily regulated sectors like defence, pharmaceuticals, utilities, aerospace, and financial services.

The Regulatory Reform Taskforce has played a pivotal role in shaping this guide and the CBI's regulatory agenda. This has served as the main platform for business engagement and a testing ground for reform recommendations.



Taking a more strategic approach to regulation requires a fundamental shift in mindset. By embracing these key thematic reforms, regulators and sponsoring departments can fulfil their statutory duties and foundational principles while also serving as a catalyst for economic growth.



- **The government should commit to adopting outcomes-based, principles-led regulation more widely**, starting with strategically important sectors such as water, and leverage the UK Regulators Network (UKRN) as a potential convener to drive innovation and best practices.



- **The government should demonstrate its commitment to leveraging standards adoption**, where appropriate, as a flexible alternative to more rigid regulatory measures. **The Regulatory Innovation Office (RIO) should initially pilot this approach** within its four focus sectors before scaling it across the wider economy.<sup>6</sup>



- **The government should commit to a targeted audit of regulatory costs, in high growth and/or enabling sectors from the industrial strategy.**<sup>21</sup> This audit should serve as a new baseline, assessing the average cost of economic regulatory compliance, to support the Department for Business & Trade's Better Regulation ambitions.<sup>28</sup>

Building on the momentum set by the Prime Minister and the Chancellor, the CBI's *A good regulation guide* provides a foundation for turning commitments into action. It outlines how central leadership on regulatory reform can strengthen the UK's competitiveness in an increasingly uncertain global landscape.

The government has shown its commitment to this goal. Co-designing a smarter regulatory framework with businesses and implementing the reforms outlined in this report can help unlock the UK's full potential and drive the economic growth that is urgently needed.



# Regulatory reform: a brief history

Regulatory reform has been a central theme in policy discourse for decades, shaping both government decision making and business operations. The evolution of regulatory frameworks reflects the dynamic interplay between economic priorities, social responsibilities, and political agendas. From the introduction of foundational safety regulations to modern debates on deregulation and innovation, the history of regulatory reform is marked by key milestones that have redefined governance and industry practices.

The timeline below provides an overview of key developments and shifts in regulatory strategies, emphasising the continuous pursuit of an optimal balance between regulatory oversight and operational flexibility across various sectors:

## The Red Tape Challenge (2011)

The Red Tape Challenge, launched in 2011 by the coalition government, aimed to reduce regulatory burdens and foster an environment for creative and credible deregulation. Despite strong political support from figures like Prime Minister David Cameron, who emphasised the need to reduce the number of statutory rules and regulations, the initiative delivered limited tangible results. While some outdated rules were scrapped, the core regulatory landscape remained largely unchanged, focusing more on headline-grabbing deregulation than addressing deeper structural inefficiencies.<sup>4</sup>

## Brexit and the Retained EU Law Bill (2016)

The Brexit debate brought regulatory reform into sharp focus, with many attributing burdensome regulations to the EU. The Retained EU Law Bill was introduced to reinforce the UK's regulatory independence, serving as a symbolic break from EU authority. However, concerns over legal uncertainty and economic disruption led to the removal of its sunset clause, underscoring the challenge of balancing regulatory autonomy with stability and investor confidence.<sup>5</sup>

### Smarter Regulation (2023)

Lord Johnson's whitepaper, *Smarter regulation: Delivering a regulatory environment for innovation, investment, and growth*,<sup>3</sup> was broadly welcomed by the CBI and the business community for its common-sense approach to regulatory reform. However, despite its aim to increase transparency, the whitepaper's proposals were never legislated and remain unrealised. While it is unreasonable to expect a new Labour government to endorse previous administration's legislation, the whitepaper provides a clear, evidence-based foundation for future regulatory reform.

### The Regulatory Innovation Office (2024)

Introduced in the Labour Party's manifesto and launched in October 2024,<sup>6</sup> the Regulatory Innovation Office (RIO) initially focuses on addressing regulatory barriers in four key sectors: engineering biology, space, AI and digital healthcare, and connected and autonomous technologies. Aiming to accelerate collaboration between regulators, encourage experimentation, and reduce growth barriers, the RIO offers an opportunity to co-design a collaborative regulatory framework. While CBI members support this initiative, it is crucial that the government properly resources the RIO to ensure it can effectively convene stakeholders and fulfil its mission.

### A new approach to ensure regulators and regulation supports growth (2025)

Launched in 2025, the government has set out its ambitions for regulatory reform in the policy paper *New approach to ensure regulators and regulation support growth*.<sup>1</sup> The paper outlines plans to reduce regulatory administration costs for businesses by 25% over this parliament, to streamline the number of regulators, and to establish a baseline for administrative costs. It also introduces a series of regulator-specific reforms designed to leverage regulation as a driver of economic growth.



## CBI activity

With regulation now at the heart of political and policy discussions, it is more critical than ever for the CBI to ensure the voice of business is heard. Over the past year, the CBI has worked closely with businesses to advocate for their regulatory priorities. To strengthen this engagement and drive meaningful change, the CBI launched its **Regulatory Reform Taskforce** in 2024. This member-led initiative has played a vital role in shaping policy recommendations and identifying how the CBI can support the development of a more effective regulatory environment.

Building on the momentum of the CBI's successful submission to the previous government's **Smarter Regulation Consultation**, the taskforce is committed to keeping regulatory reform at the forefront of the government's agenda. By providing industry-led, constructive solutions, the CBI aims to ensure that regulation fosters, rather than hinders, business growth. The taskforce is comprised of **112 direct corporate members** and **approximately 62 trade associations** through the **CBI Trade Association Council**, reflecting a diverse range of industries.

Engaged over **110** direct corporate members through the CBI's Regulatory Reform Taskforce to shape policy and drive reform.



Consulted **62** of the UK's leading trade associations via the CBI Trade Association Council to capture cross-sector regulatory priorities.

Convened the Taskforce **four times** between April 2024 and March 2025, engaging senior officials from DBT, the Regulatory Innovation Office (RIO), the Regulatory Policy Committee



Since its inception, the taskforce has convened four times—on **15 April 2024, 15 July 2024, 4 November 2024, and 18 March 2025**—bringing together leaders from various sectors and regions across the UK. These sessions have also featured senior officials from key government bodies, including the **Department for Business and Trade's (DBT) Regulation Directorate, the Regulatory Innovation Office (RIO), the Regulatory Policy Committee, and the Competition and Markets Authority (CMA)**. Their participation has enabled direct, constructive dialogue between businesses and policymakers, ensuring that industry perspectives inform regulatory decisions.

Beyond the taskforce, the CBI continues to engage with businesses through **tailored 1-2-1 sessions**, particularly in heavily regulated sectors. These deep-dive discussions have allowed the CBI to address sector-specific challenges and integrate both macro and micro issues into its broader regulatory workstream.

As the UK navigates a pivotal period for regulatory reform, the CBI remains committed to championing the needs of business, ensuring that regulation is a driver of competitiveness, innovation, and long-term economic success.

## Where do we go from here?

Through extensive engagement with the business community, the CBI has identified key regulatory barriers and developed a clear, actionable roadmap for reform—one that enhances the regulatory framework while striking the right balance between consumer protection and economic growth.

The UK has long benefited from world-class regulatory practices and globally respected regulators. Throughout the 1980s and 1990s, the UK was a pioneer in regulation and set a benchmark for other nations to follow. However, as the UK's economic landscape continues to evolve, the regulatory framework is struggling to keep pace. The Institute for Government has described this as a 'mid-life crisis.'<sup>7</sup> The UK must tackle this growing challenge head-on and resolve the question of how the government and business can strike the right balance between consumer protection and economic growth?



# Is regulation supporting UK growth ambitions?

Regulation is a fundamental pillar of the UK's economic system and shapes how businesses make investment decisions. Through extensive engagement with business, the CBI has found that firms consistently emphasise the need for a regulatory system that is:

- **Stable** – A reliable and predictable regulatory framework underpins investor confidence, particularly in times of economic uncertainty and unexpected challenges.
- **Proportionate** – The balance between regulation and business competitiveness is critical. Proportionate regulation ensures that compliance costs remain manageable, which supports the UK's attractiveness as a global business destination. This is particularly important in light of the government's new objectives outlined in His Majesty's Treasury (HMT)'s policy paper, *A new approach to ensure regulators and regulation support growth*, which aims to reduce regulatory administration costs by 25%.<sup>1</sup>
- **Smarter** – Regulation should be outcomes-focused rather than process-driven. A well-designed framework ensures that regulatory measures drive both economic growth and consumer protection without creating unnecessary complexity.
- **Innovative** – In a rapidly evolving world, regulation must keep pace with technological advancements and market dynamics, enabling businesses to innovate and embrace risk while maintaining high standards.

By prioritising these principles, the UK can foster a regulatory environment that not only supports growth but also reinforces the UK's position as a competitive and forward-thinking economy.



## Business priorities for regulatory reform

With this in mind, CBI members have formerly identified three key regulatory barriers that must be addressed to create a fairer and more effective regulatory framework. Tackling these challenges will be essential for leveraging the UK's natural strengths and ensuring that regulation acts as a driver of growth rather than a constraint. To achieve this, members have emphasised the need for strategic reforms that strengthen the current regulatory regime and address their core concerns.

These reforms could be:

1. **Provide clear accountability and support for regulators to embrace risk in regulation**
2. **Revise and enhance strategic dialogue among government, regulators, and the regulated to address poor regulatory outcomes**
3. **Tackle chronic skills shortages and capacity challenges in regulatory bodies.**

A regulatory framework built on collaboration and co-creation with the private sector can drive innovation, enhance competitiveness, and ensure compliance without stifling economic growth. With the UK's departure from the EU and its subsequent regulatory sovereignty, the government has a unique opportunity to strengthen UK competitiveness through smarter, proportionate regulation. When designed and implemented effectively, regulation—alongside the independence and expertise of regulators—plays a vital role in safeguarding consumer interests and promoting good business practices.

## The current picture

The UK's regulatory landscape is currently not delivering on the government's growth ambition. As highlighted in the report, *Rebuilding the regulatory ecosystem*, there is a persistent misconception that regulation is a cost-free tool the government can leverage, particularly during times of fiscal constraint.<sup>8</sup> In reality, regulation carries significant financial and administrative burdens for both the public and private sectors.

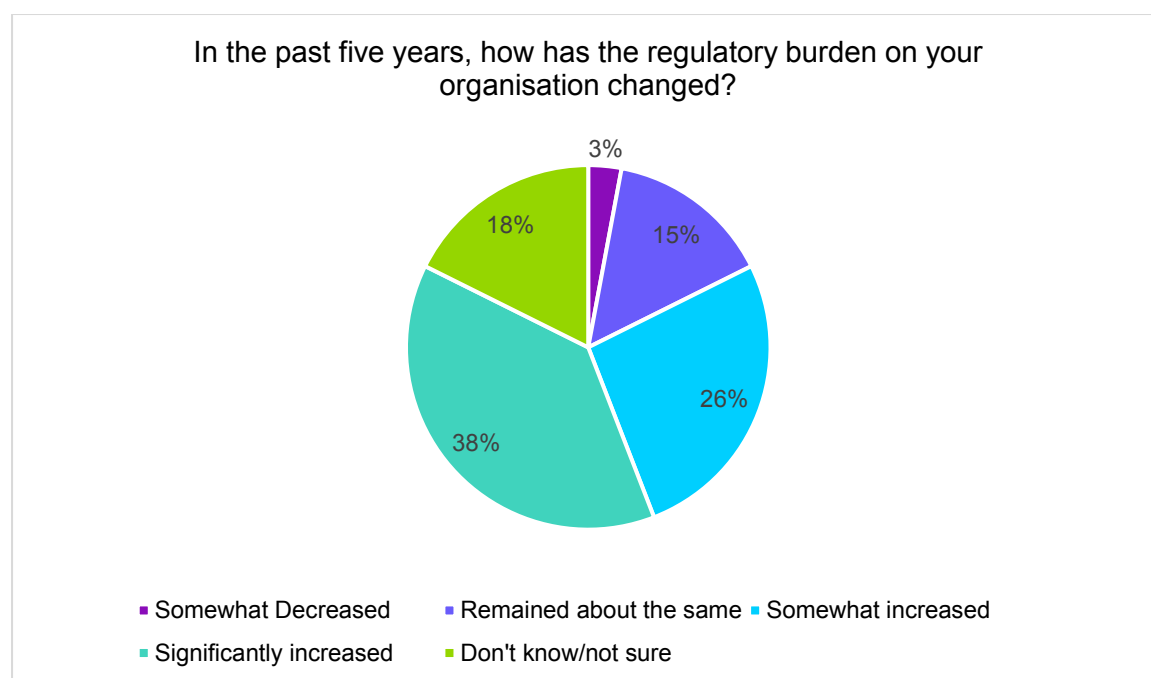
Increased regulation, by its very nature, brings an additional compliance costs, diverting valuable resources away from innovation, investment, and productivity improvements.<sup>8</sup> Therefore, CBI members welcome the government's commitment to reduce the complexity and burden of regulation, with an aim to cut administrative costs for business by 25% by the end of the Parliament.<sup>1</sup>

Findings from a **2025 CBI survey** highlight the scale of this challenge, revealing that some businesses are incurring compliance costs of up to **£50 million per year**. Furthermore, it is crucial to acknowledge that regulatory burdens are not limited to the private sector. Many

regulations impacting businesses also extend to the public sector, generating both direct and indirect costs for taxpayers and impacting the efficiency and quality of public services.

The UK economy is already feeling these effects, with **38%** of surveyed firms reporting a **significant increase in regulatory burden over the past 5 years**. A growing volume of new regulations, sector-specific barriers, and regulatory divergence post-Brexit have led many firms to perceive the UK as a less attractive destination for investment. That trend has continued over the past year, with many firms surveyed in the **CBI's 2024 Employment Trends Survey** citing the government's reforms to the labour market as a particular source of concern.<sup>29</sup> The complexity and inconsistency of the regulatory environment create inefficiencies, discourage business expansion, and hinder economic dynamism. Without meaningful reform, these challenges will continue to constrain business confidence and long-term growth.

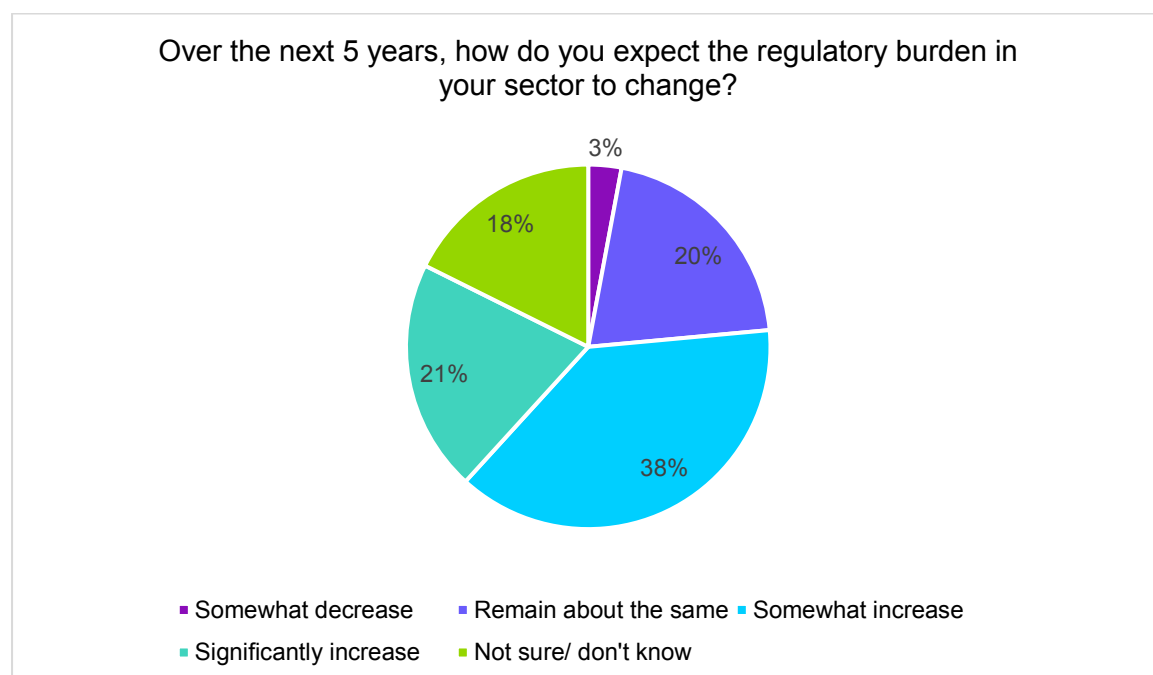
#### **CBI Survey of Businesses and Trade Associations- February 2025, over 30 of the UK's most heavily regulated firms**



The government rightly acknowledges that businesses are the backbone of the economy and that regulators can play a crucial role in driving growth.<sup>9</sup> To unlock their full potential, businesses require a regulatory environment that enables, rather than hinders, growth and investment. Mass deregulation is not the answer; smarter, targeted reforms are.

The UK needs a regulatory framework that ensures businesses with the capital to invest can do so with confidence.

### CBI Survey of Businesses and Trade Associations- February 2025, over 30 of the UK's most heavily regulated firms



### Provide clear accountability and support for regulators to embrace risk in regulation

The UK government must create an environment where regulators feel supported and empowered to take calculated risks. Such an environment will ultimately foster a more dynamic and competitive economy.

As the government acknowledges, the growing intertwining of regulatory independence with political agendas has diminished the effectiveness of regulation as a catalyst for UK competitiveness. Business leaders often point to a culture of increasing co-dependency between regulators and their sponsoring departments, creating what one CBI member has referred to as a 'parent-child dynamic' that undermines both the regulatory framework's performance and the quality of the regulations produced. A report by the House of Lords Industry and Regulators Committee highlights concerns about the influence of political factors on the appointment and reappointment of regulatory leaders, which can compromise the independence and effectiveness of regulators.<sup>10</sup>



Businesses believe that the core issue here is risk aversion, with regulators hesitant to assert their independence due to fear of unintended consequences and potential criticism. It is crucial to recognise that regulation is about balancing risk and our collective tolerance for failure. An overly cautious regulatory system can stifle innovation and hinder sustainable growth, while one that is too lax risks undermining consumer protections and market stability. CBI members have highlighted pension sector regulation as a clear example of getting this wrong; with £160bn now sitting idle in overfunded defined benefit schemes as a result of regulation over prudence.<sup>30</sup> Striking the right balance is essential to ensure that regulation enables competitiveness rather than constraining it.

In response to the Prime Minister's call for regulators to support economic growth, the Financial Conduct Authority (FCA) stressed the importance of a sustained commitment to risk-taking.<sup>11</sup> The FCA noted that embedding more informed risk-taking requires enduring acceptance, as the Chancellor has recognised, that the UK needs to prioritise resources and that there will be failures. This acceptance needs to be shared across all our accountability mechanisms, including in Parliament.<sup>12</sup> Issuing detailed guidelines and frameworks that clearly outline expectations for risk-taking and define acceptable risk levels can help regulators understand the boundaries within which they can operate, enabling them to make more informed and confident decisions.<sup>9</sup>

The FCA underscores the need for clearer guidance, political backing, greater accountability, and a cultural shift towards more dynamic, innovation-friendly regulation.<sup>12</sup> Announcements, including measures that enable the FCA to support early-stage innovative firms in entering regulated markets and the Treasury's commitment to balancing growth with proportionate risk, have been welcomed by businesses.<sup>1</sup> But this must be reinforced with concrete actions. Providing regulators with the necessary training and resources to understand and manage risk effectively is essential. This includes access to expert advice, risk assessment tools, and ongoing professional development.

Early engagement with businesses and other stakeholders on the UK's collective tolerance for risk will be crucial. Gathering feedback and building consensus on regulatory approaches can help ensure that the regulatory environment is supportive of innovation and growth.<sup>10</sup>

"The only way you get growth is via risk."<sup>11</sup>

**Lord Mayor of London**

“For too long, we have regulated for risk rather than growth, and that is why we are working with regulators to understand how reform across the board can kick-start economic growth.”<sup>13</sup>

**The Rt Hon. Rachel Reeves MP, Chancellor of the Exchequer**

## Revise and enhance strategic dialogue among government, regulators, and the regulated to address poor regulatory outcomes

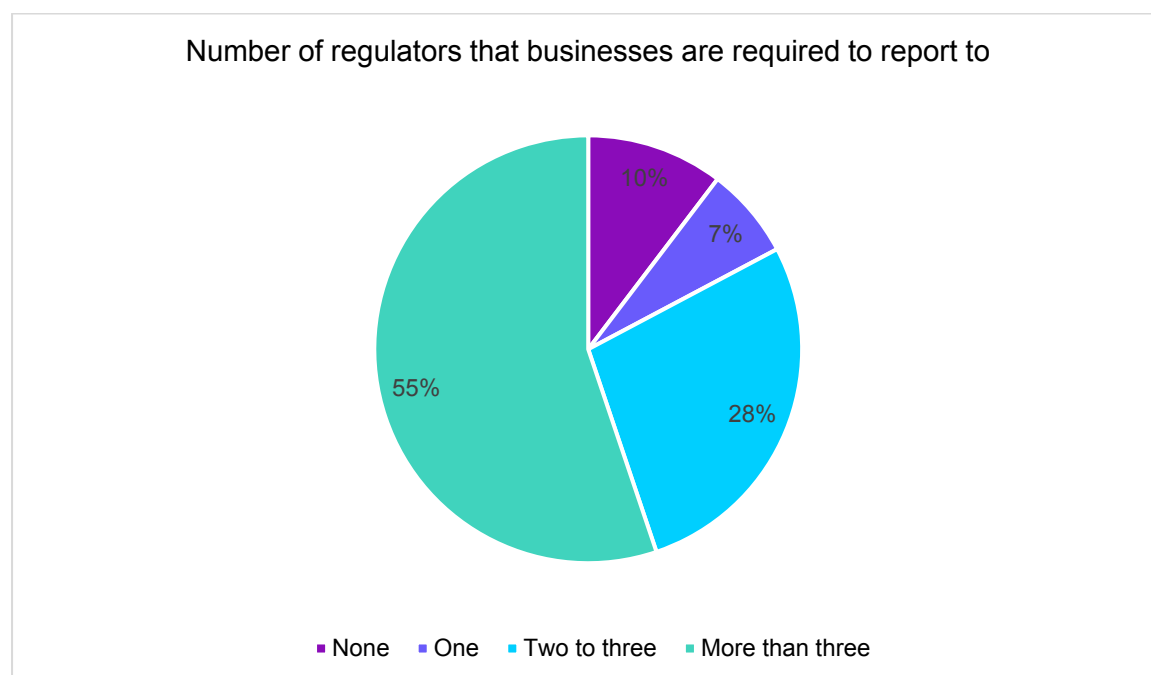
The UK Government can create a more effective and coordinated regulatory environment that supports innovation and economic growth while maintaining necessary protections.

A key barrier to a fairer, more proportionate regulatory environment is the lack of strategic dialogue between regulators, government departments, and businesses. Limited, real-terms oversight of regulators and the evolving body of regulations often leads to duplication and conflicting policies, creating excessive red tape that stifles innovation and adds complexity to the business landscape.<sup>14</sup>

The UK's regulatory framework, developed over decades through gradual policy adoption, is widely acknowledged to be in a poor state. Each regulator, created from separate legislation, has its own remit and operating practices, often leading to multiple regulators overseeing similar policy areas.<sup>18</sup> This regulatory fragmentation places a significant burden on businesses—**55% of firms surveyed in 2025** reported being accountable to more than **three regulatory authorities**, underscoring the need for a more coordinated and streamlined approach to regulation.



**CBI Survey of Businesses and Trade Associations- February 2025, over 30 of the UK's most heavily regulated firms**



Competing regulators and structural fragmentation make it challenging to evaluate the wider impacts of regulatory actions across sectors. For example, only one department, Department for Environment, Food and Rural Affairs (DEFRA), has ever conducted a full audit of its regulations, revealing a lack of understanding of the active regulatory stock across Whitehall.<sup>5</sup> Without a comprehensive overview of the UK's regulatory landscape, regulators often implement new regulations without clear visibility of their cumulative economic impact. This can lead to duplications and contradictions that place further burden on businesses.

These inefficiencies and complexities are a major source of frustration for businesses, particularly those that navigate multiple regulators with conflicting priorities. The government has announced it is taking active steps to address this issue by streamlining regulatory authorities, where appropriate, including the consolidation of the Payment System Regulator primarily within the FCA.<sup>1</sup> Yet, ultimately, CBI members stress these issues stem from a lack of clear visibility over the cumulative economic impact of existing regulations and the absence of strategic dialogue between key stakeholders.<sup>5</sup>

## Strategic coordination

As businesses have emphasised, the lack of strategic coordination among UK regulators intensifies challenges, resulting in fragmented oversight and increased uncertainty. A holistic, strategic approach involving collaboration with all stakeholders is essential for aligning priorities and objectives. Without this, the regulatory system becomes disjointed, with different parts working toward conflicting outcomes. Strategic dialogue fosters innovation by keeping regulators informed about emerging trends, and it helps adapt regulations to support new developments. It also builds trust and cooperation, resulting in a shared vision and more effective solutions.<sup>23</sup> Furthermore, publishing reports on regulatory activities, decisions, and their outcomes helps stakeholders understand the rationale behind regulations and ensures that regulators are held accountable for their actions, which can increase general compliance.

Institutions like the UK Regulators Network (UKRN) and the Digital Regulation Cooperation Forum (DCRF) were established to promote collaboration and knowledge sharing.<sup>17</sup> Though, as voluntary bodies, with no legal mandate, both the UKRN and DCRF can lack delivery powers. Without a statutory body to resolve jurisdictional disputes, and with no clear coordinating mechanism, this leaves businesses to navigate an increasingly complex regulatory landscape.<sup>10</sup> The CBI and its members advocate for a **statutory body with a clear mandate and resources** to convene regulators—ensuring accountability to Parliament and measurable success. To achieve this, **DBT and HMT must conduct a landscape review** of existing convening bodies, such as the **UKRN and DCRF**. **This review should identify opportunities to streamline and enhance collaboration, ultimately leading to the creation of a single statutory body.**

Stronger collaboration between sponsoring departments, regulators, and businesses is also essential for meaningful reform. If policymakers had greater oversight of regulatory data and the existing stock of regulations, they would be better equipped to introduce new measures that complement the current framework rather than adding to the cumulative burden. Industry stakeholders, with firsthand experience of regulations in practice, can provide critical insights for more effective policymaking.<sup>24</sup>

A co-designed approach, informed by a comprehensive understanding of existing regulations, is key to creating a balanced, efficient, and equitable regulatory landscape.

## Impact assessments (IA) and post-implementation reviews (PIR)

A major contributor to regulatory burdens and inconsistencies is the ineffective use of IAs and PIRs. These tools are designed to assess the impact of new regulations and anticipate the potential consequences of proposed policies before implementation. Their purpose is to ensure proportionality, promote effectiveness, and minimise unnecessary burdens on businesses.<sup>25</sup> However, CBI members report that their inconsistent application and weak enforcement have significantly undermined their value.

Originally introduced in 1998 as a cost-benefit analysis framework,<sup>15</sup> IAs were designed to quantify the net impact of regulation on businesses and society. In practice, firms argue that government departments often approach them as box-ticking exercises, leading to late submissions, insufficient evidence bases and poorly considered regulatory decisions. The Regulatory Policy Committee's (RPC) report highlighted this issue, revealing a sharp decline in the quality of IA submissions. Only 59% of IAs were rated as 'fit for purpose' at first submission in 2023-2024, compared to 82% in 2020-2021.<sup>31</sup> Additionally, 72% of IAs received at least one weak or very weak quality rating.<sup>16</sup> The report also documented ten instances where the RPC had to issue direct criticisms to government departments for failing to provide IAs on time or at all.<sup>26</sup> The CMA supports this view, noting that competition assessments—crucial for ensuring new regulations don't unintentionally restrict competition—are currently optional within IA's and are rarely conducted, let alone to a high standard.<sup>32</sup>

Despite these shortcomings, regulatory legislation continues to be introduced without a robust evidence base or systematic review process. The current framework makes it too easy for departments to progress with the introduction of legislation without an IA and/or an RPC opinion. This leads to evaluations that frequently overestimate benefits while underestimating compliance costs, particularly for SMEs. The RPC report further highlights a persistent failure by government departments to conduct PIRs, resulting in regulations that remain in place without proper assessment of their long-term impact. **Strengthening both IAs and PIRs is critical to ensuring that regulatory decisions are transparent, evidence-based, and proportionate to their intended objectives.**<sup>16</sup>

By addressing these issues through enhanced strategic dialogue and improved use of IAs and PIRs, the UK Government can create a more effective and coordinated regulatory environment that supports innovation and economic growth while maintaining necessary protections.

By leveraging digital tools and platforms, the government can enhance coordination and information sharing among stakeholders. Technologies such as AI and data analytics can empower government teams to strengthen their ability to monitor regulatory changes, evaluate their impact, and streamline compliance processes, resulting in more efficient and effective regulation.<sup>24</sup> Additionally, CBI members emphasise the need to provide ongoing training and resources for regulators and businesses to strengthen their understanding of regulatory requirements and foster a culture of compliance. This approach ensures regulations are implemented effectively while equipping stakeholders with the necessary tools to navigate the evolving regulatory landscape.

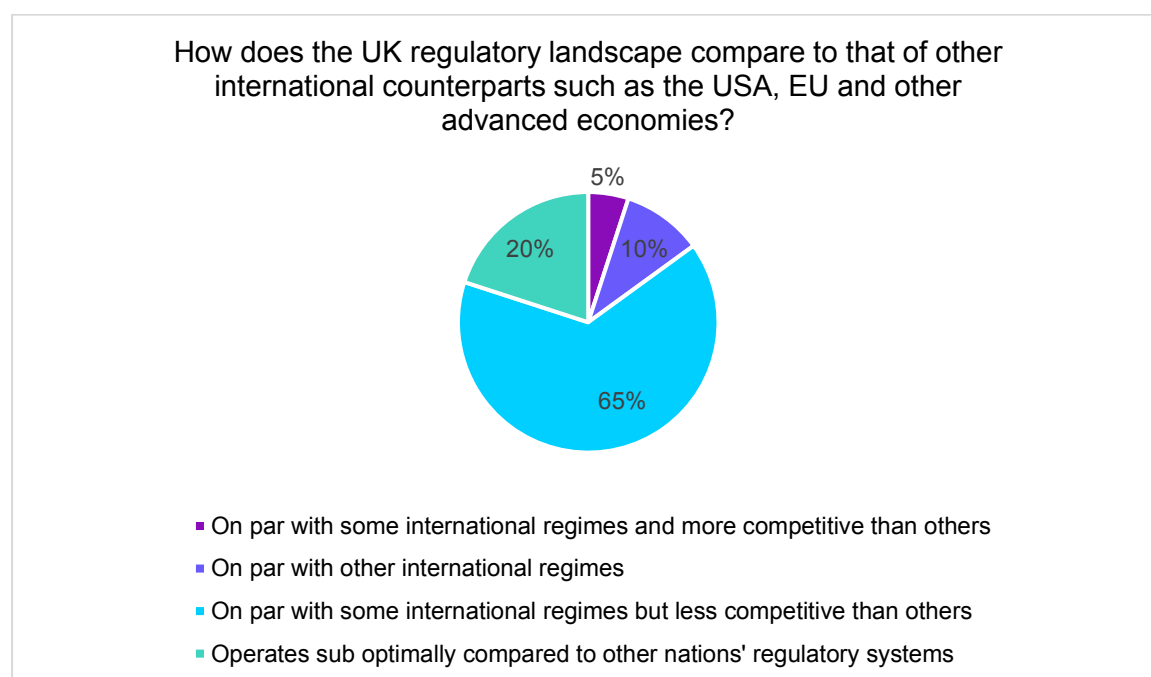
## Addressing skills shortages and capacity challenges in regulatory bodies

The UK government should ensure that regulatory bodies have the necessary resources and capacity to deliver high-quality services, thereby strengthening regulatory effectiveness and maintaining the UK's competitiveness.

### Post-Brexit divergence

The balance between regulatory powers and accountability has not always evolved in step, particularly as some regulators have taken on greater decision-making responsibilities post-Brexit. This has placed significant pressure on regulators to deliver more with limited resources, exacerbated by workforce shortages, salary inflation, and skills gaps. Consequently, businesses across multiple sectors have raised concerns about declining quality of regulation and the service regulators provide.

### CBI Survey of Businesses and Trade Associations- February 2025, over 30 of the UK's most heavily regulated firms



The House of Lords (HoL) report, *Who watches the watchdogs?*,<sup>18</sup> supports this finding, referencing growing resource shortages across regulatory authorities. Industry submissions to the report describe 'creaking regulatory capacity; as a significant issue, limiting regulators' ability to 'offer a predictable and quality service,' delaying decision making, and constraining both investment and innovation.



Efforts to monitor and reform this issue are further complicated by inconsistencies among authorities, making it difficult to compare skills and capacity challenges across different regulators. As outlined in the HoL report, each regulator is funded differently. For instance, the Health and Safety Executive (HSE) receives direct government funding, the Care Quality Commission (CQC) raises revenue through fees, and the FCA determines its own resourcing requirements through levies on regulated firms.<sup>18</sup> This results in a patchwork system of regulators with varying degrees of financial autonomy and, consequently, differing resource levels.

These widespread resource and skills shortages have been exacerbated by an influx of new responsibilities following the UK's exit from the EU. Dame Meg Hillier MP, Chair of the Public Accounts Committee (PAC), emphasised that when regulators are asked to extend their remit, they must ensure they have the necessary resources to meet these demands.<sup>18</sup> As UK regulators begin to reassert responsibility for regulatory decision making processes previously undertaken by European organisations- primarily through EU Directives- they have encountered significant challenges in meeting these demands, largely due to insufficient resources and an increasingly competitive labour market.

### **Transformative emerging technologies**

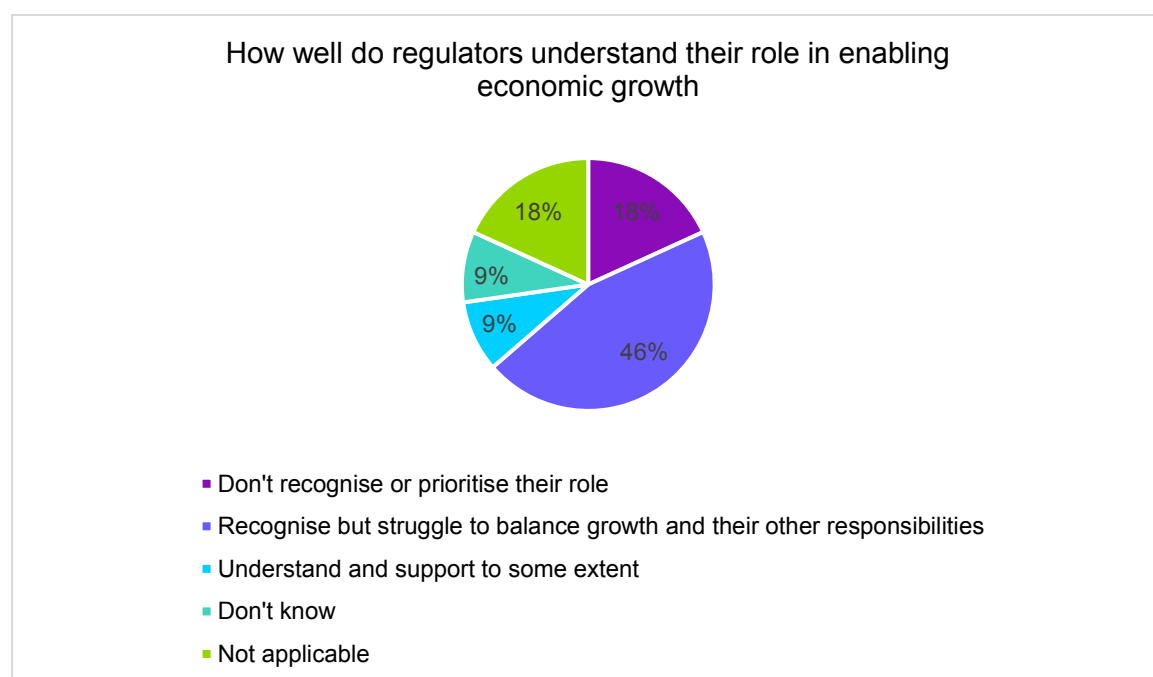
Furthermore, rapid technological advancements place increased demands on regulators, requiring them to integrate new technologies into their own processes while simultaneously overseeing and developing new regulations for emerging sectors, as well as established sectors that are being transformed by innovation. To meet these challenges, regulators must not only expand their capacity but also develop new technical expertise to keep pace with evolving market dynamics. The PAC report highlights Ofcom as a key example, noting its significantly expanded responsibilities under the Online Safety Act,<sup>18</sup> alongside its existing oversight of broadband, mobile networks, broadcasting, and postal services.

Skills gaps within regulatory bodies are particularly evident in the UK's globally significant sectors, such as life sciences, AI, and advanced materials manufacturing. While the UK has a strong reputation for research, development, and intellectual property (IP) creation, commercialising these innovations remains a challenge—not only in securing investment but also in navigating regulatory approval processes at a competitive pace. CBI members report that resource shortages and a lack of specialist expertise in regulatory agencies lead to significant delays, limiting the UK's ability to compete internationally. This issue, compounded by increased regulatory divergence post-Brexit, has weakened the UK's attractiveness as an investment destination.

It is crucial that the government ensures regulators have the capacity, resources and skills to deliver high-quality services at pace. Doing so will strengthen regulatory effectiveness and reinforce the UK's attractiveness as a competitive destination for investment.

A key priority should be strengthening international cooperation and the use of international standards. The UK must take a strategic approach to regulatory divergence, capitalising on opportunities where it offers a competitive advantage while ensuring alignment with EU regulations where beneficial to the UK and adopting European standards, which the UK continues to influence through the British Standards Institution's membership of the European standards organisations. This will help prevent unintended inconsistencies that increase compliance costs and place undue strain on regulator's capacity.

**CBI Survey of Businesses and Trade Associations- February 2025, over 30 of the UK's most heavily regulated firms**



## Thematic reforms

Despite the persistent challenges faced by the UK's regulatory regime in recent years, meaningful reform remains within reach. The UK is well positioned to build on its existing framework and reshape regulation to better serve both consumers and businesses. The focus must now shift to consolidating effective practices, streamlining inefficiencies, and addressing areas that hinder growth and investment.

This guide outlines the key thematic reforms required to ease regulatory burdens on businesses while safeguarding the best outcomes for consumers. Although significant structural challenges remain, adopting a more strategic, outcomes-driven approach to regulation that is centred around the three core principles listed below can create a stronger foundation for targeted reforms that deliver meaningful, real-world impact:

- **Outcomes-focused, principles-led regulation**
- **Integrate standards with smarter, complementary regulation**
- **Establish a robust, data-driven baseline for informed decision making.**

### Outcomes-focused, principles-led regulation

The UK's regulatory regime is often criticised for being overly rules-based and process-driven, leading to unnecessary bureaucracy and increased compliance costs. This rigid approach fails to adapt to the evolving socio-economic landscape, which impedes business growth and detracts from consumer interests. For example, businesses participating in the CBI Regulation Taskforce have argued that the UK's Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) regulation imposes unnecessary burdens on the chemicals industry by requiring the re-registration of substances already covered under EU REACH. This duplication significantly increases compliance costs without delivering meaningful improvements in safety or environmental outcomes.

This presents a critical area for discussion: what truly matters more—the process or the outcome? If the desired result is achieved, but through a different approach, does it matter how it is accomplished? This question was addressed in Ofwat's 2021 report, which argues that outcomes-based environmental regulation can deliver greater environmental benefits to society at a lower cost.<sup>19</sup>

To tackle the persistent challenges of the UK's regulatory regime, a shift toward an outcomes-based, and principles-led approach is essential. This new approach can drive economic growth while ensuring robust consumer protection. At its core, principles-led regulation establishes fundamental guidelines for businesses while granting them the flexibility to determine the most effective way to achieve compliance. When combined with outcomes-based regulation, which focuses on achieving a desired result, this approach helps to move away from rigid, prescriptive rule following and instead fosters a more dynamic, adaptive regulatory environment. By embedding both principles and outcomes at the core of regulation, the regulatory framework can remain effective, proportionate, and capable of delivering tangible benefits to both businesses and consumers alike.

Enabling firms to tailor compliance strategies to their specific needs reduces costs while delivering better outcomes for consumers. This also enables regulators to be more agile, so they can adapt swiftly to changing socio-economic conditions while maintaining proportionality.

Instilling this new mindset among regulators and sponsoring government departments will undoubtedly be challenging, but it is not impossible. There are already several positive, practical examples of outcomes-based regulation within the UK framework. One such example is the FCA's introduction of the Consumer Duty, which is widely regarded as a strong illustration of outcomes-based regulation in practice.<sup>20</sup>

While outcomes-based regulation is key to reform, it must also be inclusive and collaborative. A major risk is that the government could set outcomes unilaterally, making the shift a mere rebranding exercise from rigid duties rather than the overhaul businesses need. Mechanisms like the Regulatory Innovation Office (RIO) can embed early engagement by convening businesses, consumer groups, and regulators at the outset. This should ensure practical, proportionate outcomes; align risk appetite with regulation; and reduce unintended consequences. Broad stakeholder buy-in will also enhance compliance, enforcement, and regulatory agility.



**The government should commit to adopting outcomes-based, principles-led regulation more widely, starting with strategically important sectors such as water, and leverage the UKRN as a potential convener to drive innovation and best practices.** A joint review, led by the DBT and HMT should assess how regulators can adopt this approach effectively. Introducing clear success metrics will ensure regulation delivers intended outcomes, strengthens consumer protection, and supports market competition.

## Integrate standards with smarter, complementary regulation

Regulation has often become the default tool for addressing policy failings within industries and markets. However, regulation alone is not always the most effective or proportionate means of achieving policy objectives. Striking the right balance requires a systems approach, underpinned by robust data, clearly defined outcomes, and early engagement with stakeholders.

To achieve its ambitious goal of reducing business compliance costs by 25% this parliament,<sup>1</sup> the government must shift from a rigid, rules-based framework to one focused on meaningful outcomes. Integrating standards with proportionate, complementary regulation will be key to striking this balance.

By adopting voluntary standards—stakeholder-led guidelines that establish best practices, safety measures, and performance benchmarks without the rigidity of formal government regulations—policymakers can create a more flexible and effective regulatory environment. This approach enables the use of diverse regulatory tools, including standards supported by assurance and certification, earned recognition, and voluntary best practices, while reserving hard regulation as a last resort. To be effective, these options must be considered early in the policymaking process and informed by thorough consultation and expert input that ensures alignment between consumer protection goals and economic growth priorities. A stakeholder-led approach, that includes industry, consumers and regulators, can lead to better outcomes for everyone. This approach should first be piloted through the RIO, allowing for a controlled, evidence-based approach to implementation before broader rollout.

Realising the full benefits of smarter regulation hinges on policymakers and regulators developing a deeper understanding of how standards can serve as effective alternatives to traditional regulation or be used to support regulation through earned recognition or by providing a presumption of conformity with essential safety requirements contained in regulation. The British Standards Institution (BSI) has identified a limited awareness across government of both the practical application of standards and the advisory role of the UK's National Standards Body. This lack of understanding restricts the use of standards as a flexible, proportionate, and stakeholder-led regulatory tool, preventing policymakers from fully leveraging standards to drive innovation, ensure consumer protection, reduce burdens on businesses, and support economic growth. The UK Government's recently published *Public Policy Interest in Standardisation* is a positive development and should be promoted across government.<sup>27</sup>



**To address this, a dedicated programme should be established, including briefings for ministers, tailored training for policymakers and regulators, toolkits, and potential secondment opportunities to enhance understanding and implementation of standards.**

Utilising international standards as part of the UK's regulatory framework, and taking advantage of the UK's influence in international standards setting, can also remove barriers to trade and deliver export growth for UK businesses, particularly in emerging sectors of the economy



**The government must demonstrate its commitment to leveraging standards adoption, where appropriate, as a flexible alternative to more rigid regulatory measures. The RIO should initially pilot this approach within its four focus sectors before scaling it across the wider economy.** When combined with complementary regulation, this approach can create a dynamic and efficient regulatory environment that fosters innovation, ensures consumer protection, and supports the government in achieving its strategic goals.





## Establish a robust, data-driven baseline for informed decision making

As previously stated in this guide, a key challenge underlying this debate is Whitehall's limited understanding of the existing regulatory landscape and its cumulative economic impact on businesses. The continuous flow of new regulations, introduced with limited analysis of the impact on the existing framework, has led to duplication, inconsistency, and unnecessary compliance costs. This lack of a coherent, methodical approach to regulation—combined with inadequate performance monitoring—has resulted in a fragmented system, where regulations operate atomically rather than as part of a holistic, well-coordinated framework. Addressing this issue requires a comprehensive review of the regulatory stock to streamline and improve efficiency.

Rachel Reeves has taken a step in the right direction by commissioning a full audit of the UK's approximately 130 regulatory authorities as part of her plan to reshape the regulatory landscape.<sup>13</sup> However, the government must go further, not only evaluating the regulators themselves but also conducting a thorough assessment of the regulations they enforce.

As previously mentioned, IAs and PIRs should be mandatory when introducing new regulations and alternatives to regulatory interventions, such as standards. These assessments must not only provide a thorough cost-benefit analysis, clearly outlining the desired outcomes and associated costs, but also consider existing regulations. Often, the solution is not creating new legislation to address perceived issues, but adjusting and updating existing frameworks. However, such adjustments cannot be effectively made without a solid understanding of the current regulatory landscape and the burden already imposed on businesses.

**The government must conduct a comprehensive audit of the UK's existing regulatory framework, regardless of its origin. This process should begin with a targeted review of regulatory costs in the high-growth and enabling sectors identified in *Invest 2035*.<sup>21</sup>**

The initial audit, alongside the Chancellor's review of UK regulators, would establish a baseline, which could then be expanded across the broader regulatory landscape to provide the necessary data for informed reforms and strategic decision making.

This process will also support better use of standards adoption and outcomes-based regulation by identifying areas of duplication, contradiction, or ineffective regulatory design. When paired with properly implemented IAs and PIRs, this approach will ensure that regulation is effective, delivers intended outcomes, and avoids placing an unnecessary cumulative burden on businesses.



**The government must commit to a targeted audit of regulatory costs, in high growth and/or enabling sectors from the Industrial Strategy.** This audit should serve as a new baseline, assessing the average cost of economic regulatory compliance, to support DBT's *Better Regulation* ambitions. Using the audit outcomes to guide planned regulatory reform from the centre of government will allow the UK's pitch to the world on proportionality in economic regulation to be more empirically rooted—further enabling strategic steers to regulators to be in line with industry's cost to comply.



## Strategic regulatory reforms

The principles of smarter, proportionate regulation are essential to improving both the effectiveness of regulation and how it is perceived by policymakers. Integrating these principles into the regulatory approach will be a crucial step toward fostering the mindset shift needed to create a fairer and more balanced regulatory framework.

To drive this change, the government must take strategic action by implementing the following recommendations, integrating this policy shift within the regulatory profession, and ensuring meaningful, lasting reform.

Sector	Recommendation
Strategic reforms	<b>Commit to a targeted audit of regulatory costs in high growth and/or enabling sectors from the industrial strategy.</b> This audit should serve as a new baseline, assessing the average cost of economic regulatory compliance, to support DBT's <i>Better Regulation</i> ambitions. Using the audit outcomes to guide planned regulatory reform from the centre of government will allow the UK's pitch to the world on 'proportionality' in economic regulation to be more empirically rooted - further enabling strategic steers to regulators to be in line with industry's cost to comply.
Strategic reforms	<b>Re-commit to a Regulators Council within the government to enhance strategic dialogue between regulators and sponsoring departments.</b> This Council should be formally supported by the CBI's annual Business-Regulator Forum. It should precede Council meetings and inject the voice of the regulated into progress discussions. This will provide a more visible and signposted series of moments to assess regulatory policy reform and address the challenges and opportunities facing heavily regulated sectors and/or those on which the success of the industrial strategy relies.

Strategic reforms	<p>The government should commit to adopting outcomes-based, principles-led regulation more widely, starting with strategically important sectors such as water, and leverage the UKRN as a potential convener to drive innovation and best practices. <b>A joint review, led by DBT and HMT, should assess how regulators can adopt this approach effectively. Introducing clear success metrics will ensure regulation delivers intended outcomes, strengthens consumer protection, and supports market competition.</b></p>
Strategic reforms	<p><b>The government must demonstrate its commitment to leveraging standards adoption, where appropriate, as a flexible alternative to more rigid regulatory measures. RIO should initially pilot this approach within its four focus sectors before scaling it across the wider economy.</b> When combined with complementary regulation, this approach can create a dynamic and efficient regulatory environment that fosters innovation, ensures consumer protection, and supports the government in achieving its strategic goals.</p>
Strategic reforms	<p><b>Enhance parliamentary and select committee oversight to ensure regulators effectively balance their objectives while aligning with the government's economic strategy.</b> The DBT Select Committee and Parliament should provide clear scrutiny on regulators' capacity, resourcing, and ability to adopt risk, ensuring they have the necessary support to deliver their mandates without compromising economic growth.</p>
Strategic reforms	<p><b>The government must use its role to provide guidance to regulators on how to deliver on their statutory duties more effectively,</b> using KPIs. This should, include guidance on how to develop a Strategic Policy Statement (SPS) with a greater emphasis on effective prioritisation.</p>
Strategic reforms	<p><b>The government should support the development of resource-efficient frameworks that help businesses assess and implement innovative business models.</b> This can be achieved through initiatives such as toolkits, an FAQ helpline, and other accessible guidance resources.</p>

Strategic reforms	<p><b>DBT, DSIT and HMT should conduct a comprehensive review of existing regulatory convening bodies, such as the UKRN and DCRF, to identify opportunities for streamlining and enhancing collaboration.</b> This review should inform the establishment of a single statutory body, delivered through primary or secondary legislation. A unified entity will ensure clear accountability mechanisms, adequate resources, and an effective convening platform for businesses, strengthening regulatory coherence and efficiency.</p>
Strategic reforms	<p><b>Establish a formal industry secondment process for ensuring that regulators are staffed with employees who have industry experience.</b> This process could be facilitated by the Whitehall &amp; Industry Group to ensure no conflicts of interest.</p>
Strategic reforms	<p><b>Government departments, potentially led by DBT or HMT, should establish a dedicated program to strengthen the understanding and implementation of standards.</b> This initiative should include ministerial briefings, tailored training for policymakers and regulators, practical toolkits, and secondment opportunities to embed expertise across relevant sectors.</p>
Strategic reforms	<p>Where regulators feel that their statutory duties are in conflict, <b>they should have the capacity to request updated strategic guidance from their sponsoring department.</b></p>
Strategic reforms	<p><b>The government should launch a call for evidence on the broader tools available,</b> other than price control, to achieve long-term investment ambitions.</p>
Strategic reforms	<p><b>Sponsoring departments must ensure that funding settlements,</b> such as those for the Medicines and Healthcare Products Regulatory Agency (MHRA) which issue 'approvals or licences,' <b>are regularly reviewed to ensure appropriate levels of funding are in place</b> to deliver timely decisions around market approvals and incorporate expanding remits, including effectively regulating new technologies like AI.</p>

<b>Strategic reforms</b>	While acknowledging that regulators are funded through different mechanisms, the government must ensure they have the necessary funding <b>to provide the capacity, resources, and expertise required to fulfil their obligations under the AI Opportunities Action Plan."</b>
<b>Strategic reforms</b>	<b>Government departments, including DBT, must strengthen both IAs and PIRs to ensure that regulatory decisions are transparent, evidence-based, and proportionate to their intended objectives.</b> Government departments should collaborate closely with the RPC to make it harder for ministers to advance with legislative bills that receive a Red or Weak rating, or where AI's or Options Assessment have not been submitted.
<b>Strategic reforms</b>	<b>The government, led by either DBT or HMT, should introduce a mandatory clause that automatically sunsets regulations if they have not undergone a fit-for-purpose PIR within 6 years of coming into effect.</b> This measure will help maintain a proportionate regulatory framework and prevent cumulative regulatory creep.
<b>Strategic reforms</b>	<b>The government must consider giving the RPC a formal role</b> in verifying governments and individual departments progress towards the pledge to reduce regulatory administration costs for businesses by 25%.



### Strategic reforms

Provide sufficient resources to RIO for it to effectively carry out its remit, **and for regulators to effectively deliver their expanding remits in relation to technology and innovation, including as outlined in the AI Opportunities Action Plan**

This should include, but not be limited to, expanding the Regulatory Pioneers Fund (RPF) to £50 million over the three-year period, **with increased flexibility to support longer-term projects of strategic importance**

### Strategic reforms

**It is vitally important that business regulation affecting the UK's internal market is introduced at the same time and in the same way across the whole of the UK** and that regulatory differences across the four home nations are avoided and minimised as far as possible.

### Strategic reforms

**The framework should utilise regulatory sandboxes to create a space for businesses, regulators, academics, and consumers** to develop and test how new business models, technologies, and policies can be deployed and used in a way that is safe and responsible.



## Regulation as a driver of industrial strategy

For decades, business leaders, government, regulators, and industrialists have collaborated to shape economic priorities and drive sustainable growth in the UK. This model of co-creation—where government provides strategic direction—offers businesses clarity and certainty, allowing them to prioritise investment and respond effectively so they can remain competitive and drive profitability. In recent years, this partnership has enabled industry to navigate transformative challenges, from a global pandemic to shifts in international trade and the UK's evolving relationship with the EU. While these challenges have been significant, they have also presented opportunities for businesses to adapt, innovate, and enhance UK competitiveness.

Now is the time to build on this legacy by developing a modern industrial strategy that integrates trade, foreign policy, innovation, and sustainability while fostering deeper collaboration between government and industry. The *Invest 2035*<sup>21</sup> consultation signalled a commitment to this approach, identifying key areas where government and business must work together. A crucial element of this strategy must be the integration of regulation into a holistic industrial policy. Regulation is not just an administrative tool—it is a fundamental policy lever that will be essential in delivering the government's five key missions and broader industrial ambitions.

When multinational companies decide where to invest, they assess the regulatory landscape, favouring jurisdictions that embrace co-design and stability alongside collaborative and consultative policy development processes. While various factors influence investment decisions, long-term regulatory predictability and adaptability remain crucial. A well-executed industrial strategy must ensure that the UK demonstrates a clear, consultative, and outcomes-based regulatory framework that enhances its ability to attract global investment.

CBI members highlight that, to strengthen international competitiveness, the UK must benchmark its regulatory environment against G7 peers; effectively apply and monitor growth duties; and embed long-term, outcomes-driven frameworks. The government has committed to reshaping regulation to better support growth. For this commitment to translate into tangible economic benefits, a forward-looking industrial strategy should integrate regulatory reform as a core pillar, ensuring alignment within regulation, innovation, and economic growth.

Targeted reforms in key sectors, then, are critical. As outlined in this guide, regulatory barriers continue to stifle investment and to hinder economic performance. Addressing these challenges through sector-specific regulatory reforms will play an essential role in creating a business environment that enables sustainable growth and global competitiveness.

## Industrial strategy focus sector's

## Tactical reforms

### Digital and technologies

**The UKRN should report on the regulatory tools available to drive innovation, incorporating insights from international best practices and industry engagement.** This analysis should identify effective mechanisms to foster innovation-friendly regulation while maintaining consumer protection and market integrity.

### Digital and technologies

**The Department for Science, Innovation and Technology (DSIT) should clarify the relationship between the Regulators' Innovation Network and the resources available to regulators to support innovation.** Regulators should also diversify their toolkits for testing new business models, ensuring a more flexible and adaptive regulatory approach.

### Financial services

**DBT and HMT should impose a mandatory review of each regulation that the Prudential Regulation Authority (PRA) and FCA are responsible for, every 5-10 years, including *retrospective* cost-benefit and public comment to regularly prove it works as intended.**

### Financial services

**HMT should enhance existing powers in the Financial Services and Markets Act 2023 to deliver more effective oversight and accountability of financial service regulation.**

### Financial services

**The FCA and PRA should review and streamline their data reporting, governance and disclosure requirements, as proposed in their growth-focused letters to the Prime Minister, Chancellor and Business Secretary sent in January 2025.** Reporting should be limited to information genuinely useful for financial stability and supervisory decision-making.

	This should apply to proposed changes and existing requirements.
<b>Life sciences</b>	<b>The MHRA's operating model should be independently reviewed</b> to assess the impact of the 'one agency restructuring model' and the removal of its trading fund status.
<b>Life sciences</b>	<b>The MHRA should deepen its strategic engagement with external sources of expertise on regulatory innovation,</b> including academia and sources of cross-sectoral insight, which should include enhanced opportunities for secondments.

<b>Life sciences</b>	<p>The government and the MHRA should continue to develop and champion international recognition and reliance protocols on a unilateral basis, <b>and increasingly, a bilateral and plurilateral basis, with other countries across the globe, enhancing the MHRA's reputation as a global leader.</b></p>
<b>Life sciences</b>	<p><b>The MHRA should commit to enhancing the operation of the Early Access to Medicines Scheme (EAMS), including creating an end-to-end access route for an EAMS marketing authorisation,</b> removing duplication and replication of regulatory process.</p>
<b>Manufacturing</b>	<p><b>UK REACH must maintain the availability of chemicals that can be used safely already on the UK market, thus ensuring the future of UK manufacturing.</b> Future submissions for UK REACH must be achievable for companies of all sizes in terms of cost and resources, while maintaining protection of health and the environment.</p>
<b>Defence</b>	<p><b>The government and the Ministry of Defence should integrate any regulatory review process in the defence sector with the Strategic Defence Review (SDR).</b> Embedding regulatory discussions within the SDR will help ensure that regulations remain adaptive, proportionate, and effective in addressing evolving security and industry challenges.</p>

Defence	<p>The government and DSIT must ensure that the RIO will work in partnership with existing regulatory bodies, agencies and departments (<b>including the Civil Aviation Authority, OFCOM, Department for Transport, Ministry of Defence, and the UK Space Agency</b>) to ensure that the UK can continue to compete on the international stage in a growing global space economy.</p>
Clean energy and net zero	<p><b>The government and the Department for Energy security and Net Zero (DESNZ) should reform Ofgem's duties with a primary duty focused on realising long-term consumer value from the modernisation of an efficient energy system.</b> A small number of further consistent duties and issues to have regard should be set out in the same place.</p>
Clean energy and net zero	<p><b>Delineate more clearly Ofgem's competency and capabilities and what role it will take on policy issues alongside Department for Energy Security and Net Zero (DESNZ), National Energy System Operator (NESO) and code bodies.</b> This is vital for confidence in due process.</p>
Clean energy and net zero	<p><b>DESNZ should not proceed with proposals to simplify the process for Ofgem to impose lower-level penalties in cases where there is an objective indication of a breach.</b> This would potentially allow penalties to be issued without a thorough investigation by default. It is essential that Ofgem continues to conduct comprehensive investigations to uphold fairness and accuracy. Shifting to a guilty until proven innocent approach, where suppliers must demonstrate mitigating circumstances during an appeal, is inappropriate and could lead to unwarranted reputational damage. The only situation where a full investigation might not be necessary is when a supplier has self-reported non-compliance.</p>



Clean energy and net zero	<p>The government must ensure that funds raised from domestic shipping's inclusion in the UK's Emissions Trading Scheme (ETS) support the sector's transition to net zero. <b>These funds should be reinvested in zero-emission vessels, sustainable fuels, technology, and port infrastructure, driving the UK's decarbonisation goals and supporting a sustainable future for shipping alongside global efforts for lasting change.</b></p>
Creative industries	<p>DSIT, the Intellectual Property Office and the Department for Culture, Media and Sport must create a clear, consistent regulatory framework for AI and copyright to attract investment. <b>Ensuring strong intellectual property protections will foster innovation, support rights holders, and enhance global competitiveness.</b> A robust copyright system will further encourage investment from creative industries, solidifying the UK as a leader in AI and digital creativity.</p>
Professional and business services	<p><b>The Ministry of Justice (MoJ) should ensure that litigation is a last resort, with a stronger emphasis on faster, more cost-effective routes to redress, such as alternative dispute resolution (ADR), mediation, ombudsman services, and company complaints procedures.</b> Proportionality is key—litigation should only be used when necessary, not as the default method for dispute resolution.</p>
Professional and business services	<p><b>The government and the MoJ should introduce a cap on returns in Third Party Litigation Funding (TPLF) to ensure fairness and prevent excessive funder profits.</b> This would enhance access to justice by making funding more predictable and affordable, while safeguarding smaller businesses from profit-driven practices.</p>

<b>International trade</b>	All government departments should work towards maintaining a common commitment to base technical regulations on international standards <b>where they exist to deliver a low-friction trading environment.</b>
<b>International trade</b>	<b>The Cabinet office and the Foreign, Commonwealth, and Development Office should utilise the Trade and Cooperation Agreement's specialised committees</b> to allow both jurisdictions to work together on topics of mutual interest and discuss <b>future legislative plans</b> as they develop.
<b>International trade</b>	<b>DEFRA must negotiate a bespoke Sanitary and Phytosanitary (SPS)/Veterinary Agreement which creates some form of recognition of each jurisdiction's animal health and veterinary rules.</b> An agreement should be accompanied by regulatory coordination and, where appropriate, alignment of non-SPS aspects of food product regulation across issues such as labelling and packaging.
<b>International trade</b>	<b>DSIT should explore a strategic approach to regulation of emerging technologies,</b> cyber security, and intellectual property to foster harmonisation of rules and regulatory requirements which will better support businesses with cross-border operations.
<b>International trade</b>	<b>DSIT and the DBT should proactively engage with the EU to ensure continued cooperation on cross-border data flows,</b> aligning data protection frameworks as legislation evolves in both jurisdictions.
<b>International trade</b>	The government must work towards maintaining the <b>UK's EU data adequacy status</b> beyond the sunset clause in June 2025.

Foundational sector	Recommendation
Logistics	<b>The government must establish a national framework for strategic sectors, such as logistics, to ensure consistent standards across the UK.</b> This framework should provide clear industry requirements and offer structured guidance for local initiatives, including emission zones, road charging, pedestrianisation, and low-traffic neighbourhoods. By creating a cohesive approach, the government can reduce regulatory fragmentation, support business planning, and enhance economic efficiency while balancing environmental and community needs.
Logistics	<b>The government must implement regulatory alignment between 4.25-tonne electric vans and 3.5-tonne diesel vans.</b> Removing Heavy Goods Vehicles (HGV) restrictions, such as driver hours and tachograph requirements, would simplify fleet integration and encourage electric vehicle (EV) adoption. By lifting the five-hour training requirement and towing restrictions, this would enable the logistics sector to transition to cleaner, more efficient zero-emission vans.
Education	<b>The Department for Education should streamline the priorities of the Office for Students (OfS) to focus on quality, access, international competitiveness and financial sustainability</b> and only introduce new regulatory requirements where the public benefits are clear and the costs justified.
Education	<b>The OfS should establish a transparent risk-monitoring and assessment</b> process to guide its engagement with providers.

Real estate and property management	Remove the PRA's Building Societies Sourcebook SS20/15. <b>SS20/15 imposes unique regulatory guidance on building societies, creating an unlevel playing field. Other financial institutions aren't subject to these rules, making it uncompetitive. Repealing this sourcebook would ensure regulatory consistency and promote a more competitive financial sector.</b>
Real estate and property management	Stop the super-equivalent application of <b>Minimum Requirement for own funds and Eligible Liabilities (MREL) to mid-tier societies</b> . The super-equivalent MREL requirement ties up capital that could be used for mortgage lending. Removing this would free up resources for lending while maintaining financial stability.
Real estate and property management	Review <b>Loan to Income flow limit for first time buyers</b> . The current LTI limits restrict lending to first-time buyers, hindering the Government's housing agenda. Reviewing these limits would support greater access to homeownership and align better with housing goals.
Infrastructure	Clear guidance for the <b>Digital Verification System (DVS) is needed to ensure rent assessments reflect market conditions, offering fair returns to attract private investment</b> . Supporting local decision making and flexible funding models, like 3PD, will enable the development of community healthcare facilities. A £60 million increase in NHS rents could unlock £1 billion in investment, delivering 150 new facilities for 3 million patients.
Infrastructure	<b>HMT must set out the role of NISTA, including a long-term funding settlement that brings together the previous IPA and NIC settlements</b> . This will ensure the necessary design and delivery capabilities required to identify the most value for money projects are established to support the ten-year infrastructure strategy.

Planning	The Ministry of Housing, Communities, and Local Growth (MHCLG) must ensure Building Regulations are applied consistently to all new homes, including existing buildings converted to residential use. <b>All new homes must meet the new Future Homes Standard. Changes to building regulations should address gaps in minimum building regulations when buildings transition to residential use through a “material change of use.” This definition should explicitly encompass dwellings and flats created via permitted development</b>
Food and drink	<b>DEFRA and the Food Standards Agency must prioritise speeding up market authorisations</b> for regulated product approvals to strengthen the UK's role in food technology and innovation.
Food and drink	<b>The government must consider introducing ‘fast-track’ approval</b> for ingredients and processes already approved by trusted regulators
Food and drink	<b>The government should boost resources at the FSA</b> to approve UK-based recyclers creating new food contact materials.
Food and drink	<b>The government should streamline crisis response protocols across DEFRA, the FSA, and Devolved Administrations</b> to ensure timely decision-making and effective communication.





## Chemicals

The government should consolidate the UK's packaging reporting requirements—Plastic Packaging Tax, Packaging Recovery Notes (PRN) system, and the new Extended Producer Responsibility (EPR)—into a single annual data return. **This would reduce duplication, ease the burden on businesses across the supply chain, and free up staff capacity for more productive, value-adding work.**

## Chemicals

**Reform the Energy Savings Opportunity Scheme (ESOS) by reducing or removing fines for non-submission and shifting the focus toward regulatory follow-up on audit recommendations.** This would ensure meaningful action on identified energy-saving opportunities, while easing the administrative burden on businesses and promoting collaboration over punishment in driving energy efficiency improvements.

## Chemicals

**DEFRA and the EA should consider removing waste-related administrative and reporting requirements for participants in officially recognised Takeback schemes and closed-loop systems,** until a final waste product is produced. This would enable greater backhauling efficiency, reduce regulatory burdens, and prevent unnecessary costs and inflationary pressure, aligning regulation with modern supply chain and sustainability goals.





# Closing reflections: The vital role of regulatory reform in strengthening the business community

Rachel Reeves has stated that she 'won't apologise for wanting to reform how regulation works in Britain.'<sup>22</sup> And she is right. While the government must take a thoughtful and measured approach that avoids deregulation for the sake of deregulation, the government must also ensure that it meets its growth objectives. The potential rewards of getting this right cannot be overstated.

For the UK to reach its full potential and operate at peak efficiency, the government must reshape the regulatory ecosystem, adhering to the principles of responsible and proportionate regulation. The government must have confidence in its ability to regulate with growth in mind, embedding a greater appetite for risk within the framework while trusting that it can respond to challenges effectively and swiftly. Reforming the current system is not only possible—it is essential. While the existing structures are not fit for purpose, adopting the recommendations outlined in this report would help lay the foundation for a modern, agile regulatory environment.

The CBI hopes the government will build on the momentum it has set out and translate positive signals into meaningful reform. This is an opportunity to prove its capability and deliver lasting change where previous attempts have fallen short. Regulation is a powerful tool for unlocking the UK's full potential. By streamlining existing structures and removing unnecessary regulatory barriers, the government can make significant headway in achieving its five missions.

The CBI will continue to advocate for these reforms, collaborating closely with businesses across the UK to provide both quantitative and qualitative feedback to the government. The CBI is committed to supporting the government's ambition to reform the UK's regulatory system and will host a Business/Regulator Forum on 1st July 2025 as the first step toward co-creating a more proportionate, outcomes-based regulatory framework.

If any government departments would like further information on specific areas, CBI colleagues are available to expand on the contents of this guide. Please feel free to contact Alex Guest, CBI Senior Policy Advisor for Regulation, at [Alex.Guest@cbi.org.uk](mailto:Alex.Guest@cbi.org.uk).

# References

- 1 [New approach to ensure regulators and regulation support growth \(HTML\) - GOV.UK](#)
- 2 [Starmer asks UK regulators for ideas to boost growth - BBC News](#)
- 3 [Smarter regulation: Delivering a regulatory environment for innovation, investment and growth](#)
- 4 [Red Tape Challenge - GOV.UK](#)
- 5 [The-Future-of-Regulation-FINAL.pdf](#)
- 6 [Change Labour Party Manifesto 2024](#)
- 7 [The future of economic regulation in the UK | Institute for Government](#)
- 8 [Rebuilding-the-Regulatory-Ecosystem.pdf](#)
- 9 [Reeves calls on watchdogs to 'tear down' regulatory barriers - FTAdviser](#)
- 10 [Accountability, independence and performance of UK regulators: House of Lords committee report - House of Lords Library](#)
- 11 [Going for growth is a game of risk that ministers must embrace](#)
- 12 [FCA letter on a new approach to ensure regulators and regulations support growth](#)
- 13 [Subscribe to read](#)
- 14 [Chancellor calls on watchdog bosses to tear down regulatory barriers that hold back growth - GOV.UK](#)
- 15 [NAO Report \(HC 329 2001-2002\): Better Regulation: Making Good Use of Regulatory Impact Assessments](#)
- 16 [Government impact assessments increasingly poor quality and too late – Regulatory Policy Committee](#)
- 17 [Home | UKRN: the UK Regulators Network](#)
- 18 [Who watches the watchdogs? Improving the performance, independence and accountability of UK regulators](#)
- 19 [OUTCOMES BASED REGULATION](#)
- 20 [Consumer Duty: how to build an implementation plan for an outcome-based regulation | Insights | UK Finance](#)
- 21 [Invest 2035: the UK's Modern Industrial Strategy](#)
- 22 [Chancellor Rachel Reeves 'won't apologise' for UK reforms](#)
- 23 [us-advisory-regulatory-management-as-strategy-june-2024.pdf](#)
- 24 [8 Steps That Improve Regulatory Compliance: A Guide & Best Practices | NetSuite](#)
- 25 [https://one.oecd.org/document/GOV/RPC\(2022\)9/ANN1/en/pdf](https://one.oecd.org/document/GOV/RPC(2022)9/ANN1/en/pdf)
- 26 [RPC statements explaining missing impact assessments and opinions - GOV.UK](#)
- 27 [The UK Government Public Policy Interest in Standardisation](#)
- 28 [Better Regulation Framework - GOV.UK](#)
- 29 [cbi-pertemps-ets-report-2024.pdf](#)
- 30 [Pension reforms to go further to unlock billions to drive growth and boost working peoples' pension pots - GOV.UK](#)
- 31 [RPC publishes Corporate Report for 2023-24 – Regulatory Policy Committee](#)
- 32 [Competition assessment: guidelines for policymakers - GOV.UK](#)

# Appendix A

## BASF case study on chemicals industry

At BASF, we create chemistry for a sustainable future. We combine economic success with environmental protection and social responsibility. Around 112,000 employees in the BASF Group contribute to the success of our customers in nearly all sectors and almost every country in the world. Our portfolio comprises six segments: Chemicals, Materials, Industrial Solutions, Surface Technologies, Nutrition & Care and Agricultural Solutions. BASF generated sales of €68.9 billion in 2023.

Chemicals are rightly highly regulated for environmental and human protection, with science-based regulation being key to achieving these goals. However, regulation must also consider the complex value-chains in the chemical industry. The manufacture of a single chemical product can be multi-layered, relying on robustness, competitiveness, and efficiency throughout the value-chain.

These issues have come to the forefront as the UK implements UK REACH. Previously aligned with EU legislation like EU REACH, the UK now faces the challenge of maintaining health and consumer safety standards while supporting robust value chains for chemicals to benefit British businesses and exports.

To illustrate this complexity, BASF, a major global chemical producer, conducted a value-chain analysis for a range of products manufactured at one of its UK sites. The finished chemical product at this site sits at the sixth level of the value chain, requiring a synthesis path with at least fourteen precursor chemicals over five value-chain levels. Typically, a chemical manufacturer only sees their immediate supplier and customer levels, meaning chemicals in these value-chains may be produced by multiple companies across various international locations. For BASF and many UK chemical producers, remaining part of European and global value-chains is crucial for competitiveness, necessitating regulatory pragmatism and proportionality.

A key aspect of UK REACH, mirroring its EU counterpart, is that it did not run continuously from the UK's exit from the EU. Consequently, British businesses must repeat the registration of chemicals for the GB market, involving the collection of safety and use data. The European Commission estimated EU REACH registration costs at €5 billion. With GB industry replicating this, British companies may have to pay again for registration dossier information or repeat studies, including animal studies. BASF estimates its compliance cost at approximately £70 million, while Defra's impact assessment estimates industry costs between £1.3 and £3.5 billion. This cost factor could distort the UK chemicals market, leading to some substances disappearing or becoming more expensive due to additional regulatory overhead costs.

To remain competitive, the UK chemicals sector and downstream industries have long campaigned for a more pragmatic and proportional approach to UK REACH registration. A key aspect that trade bodies have been advocating is the recognition of the compliance of EU-sourced chemical products without re-registration for use in Great Britain.

Following extensive consultation, in November 2023, Defra indicated that an alternative registration model is being considered, potentially reducing the estimated £2 billion costs to industry. This is a welcome step, and industry will continue to engage with policymakers as detailed proposals emerge.

Defra also aims to refine the information on 'use and exposure' that GB registrants must provide to fully understand and manage risks. Enhanced granularity on substance use has been desired by suppliers for years but is challenging due to complexity and confidentiality within multi-level value-chains.

Progress on UK REACH is positive, and adopting a pragmatic approach will minimize costs, bureaucracy, and trade barriers without lowering standards. This will showcase the UK's commitment to a predictable and proportional policy framework for regulating the chemicals sector, supporting manufacturing sectors with critical raw materials. Recognizing compliance of EU-sourced goods would allow UK chemical users to continue sourcing from a competitive supplier market without additional costs and workload duplication.

## Appendix B

### AIRTO & Alden Legal case study on space industry

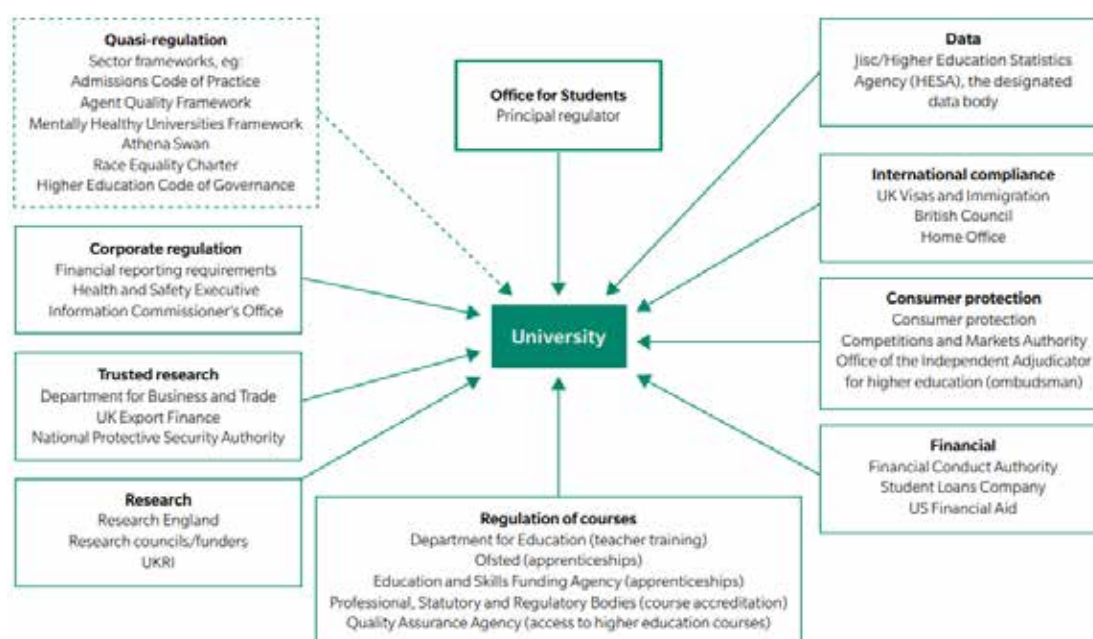
The space industry in the UK is a high growth and high innovation sector. Initially satellites were launched singly into space and the regulatory licensing regime developed to primarily regulate individual satellites. However over recent years the sector has changed rapidly due to the falling cost of building and launching satellites, which has meant that it is now much easier and more cost effective to launch a constellation of satellites, with the acceptance that some satellites may fail but the constellation can still operate. However, regulation, policy and insurance requirements have not fully adapted to this change. Regulators inability to adapt to the changing space market, embrace innovation, focus on the outcomes and anticipate technological changes has inhibited the sector's growth. This has led to many companies leaving the UK and relocating abroad where regulation has been more flexible and government 'customer service' more effective. This has led to the UK losing out on the development and scaling of UK-based space research. However, regulators have begun to work more closely with the sector and to understand their business plans, objectives and evolving industry landscape, as seen in the recent DSIT regulatory review. But change must now be implemented in the UK at a Department and regulator level.

# Appendix C

## Universities UK case study on regulatory burden

Universities UK (UUK) is a membership body which acts as the collective voice of over 140 universities. We work with the government and higher education sector to champion UK higher education. The sector's regulators differ between the four nations of the UK. In England, in addition to the principal regulator the Office for Students (OfS), universities are answerable to multiple regulatory and funding bodies across all their activities. Universities have reported working with as many 140 professional, statutory and regulatory bodies (PSRBs) to assure course quality.

**Figure 1:** A typical English university and its regulation



There is no single public body responsible for taking a strategic, system-wide view of the overall health of the sector in England. The result is often excessive, duplicative, and sometimes contradictory requirements. This generates a heavy regulatory burden. On average a university has a 17.6 FTE staff dedicated to regulatory compliance, while 45% of universities say that regulation takes up a significant or major proportion of governing bodies' time. This restricts universities' ability to innovate and transform, and puts a strain on scarce resources.



There have also been concerns about government interference. Between 2018 and October 2023, the OfS was subject to 27 separate pieces of published government advice. Many legitimately related to funding, where some prescription around government priorities is justified and appropriate, but others went further and spelled out the specific approaches the OfS should take. This, combined with the Secretary of State's extensive powers of appointment over the OfS board and senior executive team, led to a widespread view across the sector that the independence of the OfS had been compromised.

In turn, there has been a loss of trust which has resulted in a strained relationship, reported in research commissioned by the OfS. Over the last few years the OfS has made efforts to improve communications and relationships with the sector, which have been welcomed. It is essential that this work continues as the OfS develops its new strategy following the [Behan Review](#).

As well as improving its communications with the sector, further possible solutions to address these challenges include:

Adoption of a consultative cost-benefit methodology to review current and proposed regulation, based on the existing HESA 'burden assessment methodology'.

Establishment of a transparent risk-monitoring and assessment process to guide engagement with providers. For providers judged low risk, regulatory burden could be reduced, giving providers the confidence to embark on innovative approaches

Demonstration of greater engagement with students and the sector. We support the OfS's intention to develop a student interest board. Our view is that this should be complemented by establishing an independent provider panel, alongside closer working with sector groups and networks.

Closer coordination across government and its statutory and regulatory burdens, considering the cross-cutting implications of regulation and oversight by different bodies and the overall regulatory environment. This could create a smarter, leaner system.

## Appendix D

### Foundation Industries Ventures (FIVE) case study on regulation and innovation

Link to reports to add in wherever best... <https://fiventures.org/news/regulation-&-innovation-reports/>

Foundation Industries Ventures (FIVE) supports and enables sustainable, innovative growth for start-ups and spinouts in the Foundation Industries (FIs) of cement, metals, chemicals, paper, ceramics, and glass. FIVE provides wrap-around support including business sprints and access to investors, mentors, and equipment across leading UK scale-up centres to accelerate development and commercialisation of sustainable innovation for the energy-intensive FIs.

FIVE is supporting government through FIVengage, its regulatory science and innovation network that promotes innovation by leveraging collective resources and expertise to establish robust regulatory frameworks that support and accelerate scientific and technological advancements. FIVengage carried out research into regulatory barriers within the FIs to support future interventions or activities thanks to funding from the Regulatory Science and Innovation Network competition delivered by Innovate UK as part of UKRI.

In partnership with AMION and Civikas the research identified three main barriers to innovation and potential solutions.

#### Economic regulations

- **Market entry and compliance:** New businesses face substantial regulatory hurdles with varying market standards. Streamlining processes and creating cross-sector standardisation can aid market entry.
- **Pricing and incentives:** SMEs face high costs and limited capital. Government support to low-carbon products and creating market incentives are crucial. Regulatory impacts on demand and pricing, especially for waste-derived products, need addressing to foster recycling and innovation.
- **Access to capital and training:** SMEs often struggle with capital access and training not suitable for industry needs. Enhanced support and training are necessary.

## Industry Regulations

- Environmental protection: Inflexible regulatory frameworks can hinder technology rollouts to reduce carbon emissions. Inefficient recycling processes and costly licensing for material reuse pose significant challenges.
- Planning and permitting: Slow permitting processes and the need for specialist facilities cause delays. Effective coordination in planning and place-based regulations, especially for industrial clusters and carbon capture, is critical.
- Health and safety: Compliance is vital but delays in consumer protection regulations can impact product innovation and market entry.

## Institutional Regulations

- Intellectual property: Onerous IP agreements and lengthy negotiations between businesses and academia can obstruct collaboration. Streamlining IP arrangements and adopting standard contracts can facilitate partnerships.
- R&D agreements: Larger companies have a resource advantage in early-stage research, which can dissuade smaller firms from engaging in collaborative R&D. Reducing the complexity and time required for IP agreements can enhance participation.

Regulatory alignment between the UK, EU and trading partners worldwide, the need for sandboxes to help streamline the testing and permitting of new products, addressing the skills gap, and aligning training with industry needs were all highlighted as cross-cutting themes.

And while regulations are essential for environment and health protection, they must be balanced to avoid impeding investment, innovation, and competitiveness. Varying by sector and company, the overarching challenges to innovation revolve around high costs, complex compliance requirements, IP, and inconsistencies in environment legislation, particularly carbon emissions.

The suggested solutions are many but simplifying standards, improving funding access, creating regulatory sandboxes, and facilitating advocacy networks were all seen as gamechangers to removing regulatory barriers and fostering innovation.

## Appendix E

### Smith & Nephew case study on medical devices and medtech

It is important that medical devices are regulated to ensure patient safety and clinical efficacy. The UK's Medicines and Healthcare Regulatory Agency (MHRA) is responsible for the regulation of medical devices in the UK. Since leaving the EU, the UK has needed to build a new regulatory framework for Great Britain, and over that time has had significant engagement with industry. Northern Ireland has continued to remain aligned with the EU for Device Regulation.

In the European Union (EU), the regulation of medtech is under central EU regulation the "Medical Devices Regulation (MDR)". There is not a central EU regulator for medtech, instead a system utilising Notified Bodies (the counterpart of Approval Bodies in Great Britain) companies was created, whereby they are paid by manufacturers to regulate a product and there is a responsibility to the member states' national regulator (competent authority). Products that are regulated receive a certificate that allows the manufacturer to use the CE Mark.

Since leaving the EU, the UK has recognised the EU's CE Mark for GB and will continue to do so until at least 2030 for some devices. The UK is now in the process of developing a reliance system where manufacturers will be able to continue to utilise the CE Mark in GB. Since 2022 UK Government and the MHRA have also been considering recognising regulatory clearances and approvals for some products from trusted international regulators, including the US's FDA.

Globally companies duplicate the regulation of medical devices numerous times, whilst adding no additional value to the product, or improving to its patient safety. Given that the UK is a small global market, it puts the UK at a disadvantage.

The UK's MHRA has the foundations to be the home of a world-leading and globally admired medical technology regulator, in the way that it is for pharmaceuticals. However, the current direction of travel of policy appears to replace the duplication of regulation, with a different type of duplication and therefore will not realise the opportunity for the UK or the MHRA. The MHRA needs to be the centre of medtech regulatory expertise, it needs the ability to recruit medtech regulatory experts and it should deliver value for money for industry. If the MHRA undertakes the medtech regulatory process, industry could pay the MHRA directly. Currently the MHRA is proposing that industry increases payments to it, whilst not delivering any extra services or value, disincentivising industry from launching products in Great Britain.

# Appendix F

## Case studies prepared by PAGB, the consumer healthcare association

### Case Study 1 – ePI (electronic patient information)

The transition from paper-based patient information leaflets (PILs) to electronic patient information leaflets (ePILs) for medicines represents an opportunity to enhance healthcare for patients and improve efficiency within the NHS. A shift to digital-first medicines information aligns with the Government's broader goals of sustainability, digital innovation, and equitable access to healthcare information. Having support for this initiative from the regulator ensures the UK is not left behind by other countries which are moving to a digital-first approach to medicines information but also provides the pathway needed for the legislative changes required.

The UK Electronic Patient Information Task Force (UK ePI task force), a cross-industry collaboration supported by the Association of the British Pharmaceutical Industry (ABPI), the British Generic Manufacturers Association (BGMA) and PAGB, the consumer healthcare association, was initiated in 2023. The task force consists of industry volunteers and key stakeholders including the regulator, MHRA.

However, despite a positive initial engagement period, the task force has not had any MHRA input since May 2024, causing significant delays and uncertainty regarding the timing and commitment on the transition roadmap to ePI.

We understand the cause of this to be resourcing and prioritisation within MHRA as well as clarity around the new government's priorities. We need timely input, to avoid UK regulation and innovative thinking to fall behind and to take advantage of the positive work being activated through a cross-industry initiative where the motivation and engagement level is high. The ability to take calculated risks without the need to have political oversight at every stage will be key.

## **Case Study 2 – Medical device regulations**

Medical devices supplied to Northern Ireland (NI) must comply with the terms of the Windsor Framework and therefore must be compliant with the medical device regulation in EU and bear the CE mark. Consequently, to enable distribution throughout the UK, medical devices must be in compliance with the UK Medical Devices regulation and the EU medical devices regulations (MDR). At present, CE markings are recognised in GB under these regulations and therefore, manufacturers can apply one set of regulatory requirements to their products in the UK.

However, this is only for a time limited period and going forward MHRA intend to introduce updated regulation in GB. As part of their recent consultation on proposed routes to market, the MHRA has proposed introducing additional GB-specific conformity checks for products already approved by trusted international regulators. This would increase regulatory complexity and bureaucracy, significantly raising costs and extending timelines with no apparent added value.

These proposals risk deterring manufacturers from prioritising the UK market, threatening the availability of vital medical technologies relied upon daily by NHS patients and those wishing to manage their own conditions. This is not only above and beyond the requirements that are needed for NI alone but is also inconsistent with the long-term acceptance of CE marking in other sectors in the UK.



### **Case Study 3 – Reclassification**

In 2023, the Reclassification Alliance was reestablished, a collaboration coordinated by PAGB, the consumer healthcare association, alongside the Department of Health and Social Care, the Medicines and Healthcare products Regulatory Agency (MHRA) and pharmacy organisations. Thanks to the work undertaken by the alliance, in February 2025, the government published a new list of medical conditions and categories where it is encouraging more reclassification applications to the MHRA. This is an opportunity for manufacturers in the consumer healthcare sector to widen their portfolios and deliver new OTC products across categories including short-term sleep aids, oral health, pain management, allergic rhinitis, skin conditions and women's health conditions.

Widening access to medicines through reclassification means patients can access more of the medicines they need in a rapid and convenient way without having to visit their GP. It is of huge benefit to the NHS and economy too: a 5% reduction in NHS prescribing spend due to reclassification would result in £1.4 billion saved in prescription and appointment costs<sup>1</sup>.

While this is major step forward for self-care in the UK, and a great example of how collaborative working can facilitate engagement with regulators. We need to ensure that the MHRA can effectively process new reclassification applications, and this requires urgent reform of MHRA's reclassification process to recognise the innovative nature of this work. Without it, we risk losing the opportunity to fully unlock the benefits of wider access to OTC medicines. Ensuring the MHRA has the resources and regulatory flexibility needed will be critical to supporting innovation and delivering improved self-care options for the public.

April 2025

© Copyright CBI 2025

The content may not be copied, distributed, reported or dealt with in whole or in part without prior consent of the CBI.

Special thanks to Alex Guest, Nicky Williams, Devon Geary, Nicola Eckersley-Waites, Naomi Watts, John Foster, Jordan Cummins, and Rupert Soames for their contribution to and involvement in this guide.