



# **A Business-Centric Approach to Cutting Red Tape**

STUDY



European Economic  
and Social Committee



# **A Business-Centric Approach to Cutting Red Tape**

## **From Complexity to Clarity: Reducing EU Regulatory Burdens with AI**

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## General information

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MAIN CONTRACTOR	<i>Sira Consulting B.V.</i> <i>Herculesplein 88,</i> <i>3584 AA Utrecht</i> <i><a href="mailto:info@siraconsulting.nl">info@siraconsulting.nl</a>, <a href="http://www.siraconsulting.nl">www.siraconsulting.nl</a></i> <i>+31 (0) 30 602 49 00</i>
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AUTHORS	<i>Team Sira Consulting/Y-digital</i>
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CONTACTS	<i>Peter Bex</i> <i><a href="mailto:Peter.bex@siraconsulting.nl">Peter.bex@siraconsulting.nl</a></i> <i>+31 (0)6 5242 0108</i>
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## **Abstract**

Regulatory burdens in the EU have increased despite simplification efforts, impacting business competitiveness, particularly for SMEs. This study, commissioned by the EESC, analyses regulatory expansion, evaluates the effectiveness of the Better Regulation (BR) framework, and explores AI-driven solutions to reduce regulatory burden.

The research follows a structured four-phase approach:

- Regulatory Burden Analysis – AI-driven assessment of regulatory expansion (2019-2024) and evaluation of BR tools.
- AI-Based Monitoring – Development of AI models to extract compliance obligations from legal texts.
- Regulatory Burden Index (RBI) – Definition of heuristics and metrics to quantify regulatory burdens, tested on selected EU regulation.
- Policy Recommendations – Validation through stakeholder engagement (interviews) and proposals for integrating RBI into EU policymaking.

This study highlights that even well-researched, broadly supported policies can create unintended burdens if they fail to integrate seamlessly with business operations. Effectively reducing regulatory burden in the EU requires addressing a fundamental issue in the current approach: the overreliance on ex-ante assessments to estimate regulatory impacts. A more harmonized and flexible regulatory approach is essential to ensuring that sustainability policies achieve their goals without excessive administrative burdens or undermining global competitiveness.

The Regulatory Burden Index (RBI) provides real-time insights into compliance costs, complexity, and national implementation inconsistencies. The SME Indicator Company Approach measures sector-specific regulatory burdens.

To reduce regulatory complexity, the study recommends:

- Implementing the RBI to assess and prevent excessive burdens.
- Strengthening the BR framework with clear reduction targets.
- Ensuring adaptive legislation to prevent compliance uncertainty.
- Harmonizing implementation across Member States to enhance predictability.

By leveraging AI-driven insights, the EU can streamline regulations, making them more effective and business-friendly.

## Executive summary

### 1. Regulatory expansion and competitiveness impact

Although **businesses recognise the importance of clear and effective rules**, and are not opposed to regulation in principle, they are increasingly burdened by rules that are unnecessary or more complex than needed. The volume of EU regulations has steadily increased despite initiatives aimed at simplification. While previous efforts yielded some reduction in legislative proposals, **the overall regulatory stock continues to grow** at a faster pace than in comparable economies. This expansion is further exacerbated by three **underlying factors**: (1) the vague and abstract formulation of EU legislation, which leaves businesses uncertain about implementation; (2) diverging national interpretations, leading to fragmentation within the Single Market; and (3) insufficient alignment with existing regulations, creating overlaps and contradictions. The cumulative effect of these factors executed by the regulators outlined in the picture below, **significantly amplifies the complexity of compliance for businesses**.

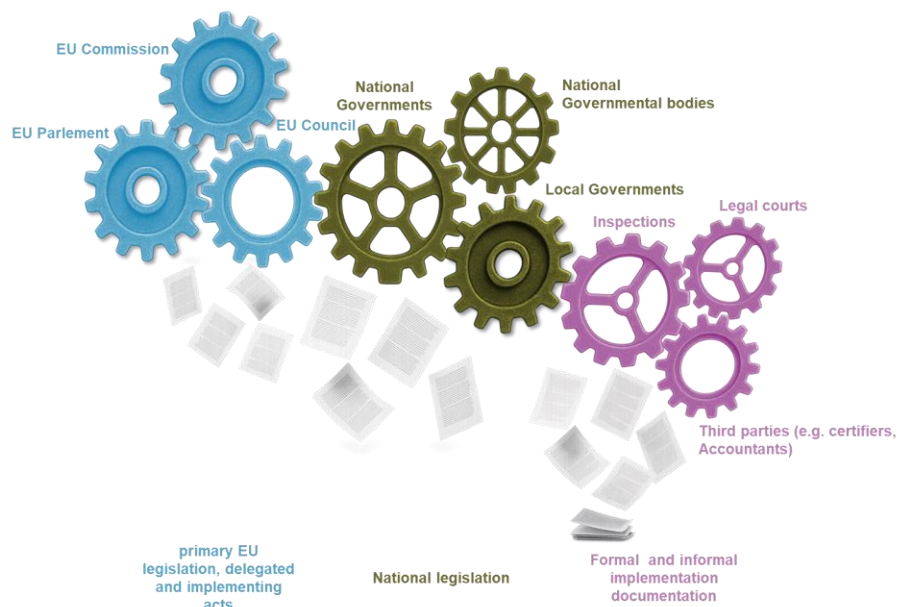


Figure 1 Overview of EU Regulators

### The heavy burden on businesses and compliance peaks

For companies, the true weight of regulation is **not just the sum of individual legal obligations but the cumulative burden of multiple regulations accumulating over time**. Businesses, especially small and medium-sized enterprises (SMEs), face continuous waves of new rules that require ongoing adjustments, leading to additional costs, administrative burdens, and uncertainty. Regulatory peaks, periods where multiple new obligations take effect simultaneously, further exacerbate these challenges. **Companies must rapidly adapt their processes, allocate resources to compliance, and often rely on costly external consultants**. This diverts attention and investment away from core business activities such as product development, innovation, and market expansion, ultimately reducing productivity and competitiveness.





## Beyond costs: the workability of regulation

Beyond financial costs, businesses **also struggle with the workability of regulations**. Many rules are unclear, difficult to implement, or misaligned with the operational reality of companies. SMEs are particularly vulnerable to these challenges, as they lack the internal resources to navigate regulatory complexity effectively. Regulatory fragmentation across EU Member States further complicates compliance, creating an uneven playing field where some businesses face stricter requirements than others. **This hampers competition and restricts the ability of firms to operate efficiently within the Single Market.**

### A business-centric approach

To ensure that regulatory reforms lead to tangible improvements, **policymakers must adopt a business-centric approach, with a particular focus on SMEs (Think Small first)**. Excessive regulatory burdens are not just a bureaucratic inconvenience, they directly impact productivity, making European companies less competitive in global markets. If the EU does not act decisively to streamline regulations, businesses will continue to face increasing compliance costs and operational inefficiencies. As highlighted in the Draghi and Letta reports, **Europe must take swift and effective action to cut red tape**, ensuring that regulations support, rather than hinder, economic growth and competitiveness.

## 2. The EU's Better Regulation Program: ambition vs. reality

The European Union has developed an extensive Better Regulation (BR) program to improve the effectiveness, efficiency, and transparency of EU policymaking. This initiative aims to ensure that regulations are evidence-based, proportionate, and future-proof. The program consists of two main pillars: **impact assessments for new legislation and evaluations of existing regulations**. In this framework the European Commission has established a.o. tools such as the **SME Test, Competitiveness Check, and the Regulatory Scrutiny Board** to prevent excessive regulatory burdens. Additionally, **the REFIT and Fit for Future** platforms were created to review and streamline existing rules. Despite these structured efforts, businesses, especially SMEs, continue to experience significant regulatory burdens, limiting their competitiveness and growth.

### Four lessons on why the Better Regulation Program has not delivered

The challenges businesses face due to increasing regulatory burdens align closely with the structural shortcomings of the Better Regulation program. While these burdens are often experienced at the operational level, their root causes lie deeper in the EU's legislative process. The failure of existing mechanisms to deliver real relief can **largely be attributed to a lack of strong political will to enforce clarity, consistency, and accountability at every stage** from drafting to implementation. This absence of commitment has enabled four persistent lessons in the regulatory approach to remain unaddressed:

1. **Regulation as a moving target** – Just as businesses struggle with vague and evolving rules, the EU legislative process itself introduces continuous changes. Political negotiations frequently alter regulatory content, leading to unforeseen compliance obligations that were not initially assessed.
2. **Vague and incomplete legislation** – EU laws often lack clarity, forcing businesses to navigate uncertainty until the specifics are determined by post-adoption of delegated acts, national

legislative implementation and interpreted by supervisors and courts. The Better Regulation process does not address this issue as it defers critical details to later stages, leaving practical feasibility largely unexamined, therefore postponing investment decisions.

3. **Fragmentation due to national implementation** – The flexibility granted to Member States in transposing directives results in regulatory divergence, reinforcing the business challenge of inconsistent obligations across borders. Despite efforts like the REFIT program, the Better Regulation framework has not effectively harmonized interpretations across the EU and cannot do so in its actual set-up.
4. **Unmeasurable and ineffective reduction targets** – Beyond these persistent issues, a weakness of the Better Regulation program is the absence of clear benchmarks for measuring regulatory burden reductions. While initiatives like One-In-One-Out (OIOO) and reporting burden cuts set ambitious goals, they lack a transparent methodology, making their impact difficult to assess and limiting their effectiveness in delivering tangible relief for businesses. Clear objectives and effective monitoring require political and administrative will; without strong leadership and a firm stance against legislative ambiguity or ineffectiveness, such flaws are likely to persist across all levels of the regulatory process

#### **Four preconditions for an effective EU Regulatory burden reduction program**

Effectively reducing regulatory burden in the EU requires addressing a fundamental issue in the current approach: the **overreliance on ex-ante assessments to estimate regulatory impacts**. To create a meaningful and measurable reduction in regulatory burdens, the EU must adopt a more structured and business-centric approach. Based on best practices and lessons learned from previous initiatives, four key conditions are essential for an effective regulatory reduction program:

- Focus on **low-burden policy instruments**.
- New regulations: **Robust control** and consistency over the whole process of law-making (**including implementation in Member States**) and digitalisation of laws in individual segments – provisions and obligations - and their enrichment with the necessary metadata.
- Existing regulations: Clear, **quantitative reduction targets** based on measurable data and a transparent methodology for a baseline measurement and monitoring the reduction target.
- An **enforcement mechanism** to ensure objectives are met and regulatory burdens are effectively reduced.

#### **3. The AI-supported Regulatory Burden Index**

Regulatory burdens within the EU remain fragmented and inconsistently assessed. While the Standard Cost Model (SCM) is used to estimate regulatory costs, its application is inconsistent across legislation, and Member States implement EU rules differently. Additionally, current impact assessment methods are time-consuming, lack uniformity, and fail to provide real-time insights into regulatory burdens. This lack of standardization hampers effective policy evaluation and limits the ability to develop targeted reduction strategies.

## Purpose of the Regulatory burden index

The *Regulatory Burden Index* serves as both an analytical and preventive tool designed to quantify and evaluate the administrative burden imposed by existing and proposed legislation. It aims to:

- Provide a **structured measurement** of regulatory costs and workability.
- Offer **real-time insights** to policymakers, allowing them to identify and mitigate unnecessary burdens.
- Ensure **greater transparency and comparability** of regulatory burdens across different Member States and sectors.

## Structure and functioning

The development of the index was guided by a pilot in which AI was used to translate expert knowledge on regulatory burden quantification into **heuristics and metrics**. This approach was systematically tested on EU legal texts to determine how the index could be operationalized in practice. The resulting methodology consists of four key components:

1. **Quantification of regulatory burden** – The system evaluates compliance costs based on metrics such as time investment, external costs, reporting frequency, and affected businesses.
2. **Automated text analysis** – AI identifies obligations within legal texts, extracts relevant regulatory information, and scores legislation based on burden severity.
3. **Comparative analysis** – The index ranks regulations based on the level of burden they impose, making it possible to compare different laws or national implementations and their impact on businesses, particularly SMEs.
4. **Actionable recommendations** – The tool not only assesses burden but also suggests ways to streamline obligations and improve regulatory efficiency.

By **testing the index against actual EU regulations**, the methodology has been refined to ensure practical applicability, making it a reliable instrument for identifying excessive administrative burdens before they affect businesses.

## Challenges and future outlook

Key challenges include **inconsistencies in legislative texts, unclear implementation details, and the risk of AI-generated inaccuracies**. To address these, the index relies on supervised AI models with expert validation, ensuring accuracy and relevance. Looking ahead, improvements in **generative AI technology, interactive policymaker feedback loops, and a standardized EU-wide methodology** will be crucial in refining the tool's effectiveness.

By integrating data-driven regulatory assessments, the Regulatory Burden Index can serve as a cornerstone for smarter policymaking, reducing unnecessary regulatory burden while maintaining regulatory effectiveness.

## 4. Recommendations

To effectively address regulatory burdens, an EU strategy is required that both prevents unnecessary burdens from new legislation and focuses on reducing existing burdens. The recommendations below are structured around four preconditions for an effective EU Regulatory burden reduction program.

### A. The next step in Better Regulation: develop an AI-supported Regulatory Burden Index

The European Union lacks a **fast, structured, and comparable** method to assess regulatory burden across EU legislation and its national implementation. This pilot developed preliminary version of the Regulatory Burden Index which is an analytical and preventive tool that **quantifies and evaluates the regulatory burden** of both existing and proposed legislation by integrating **AI-driven analysis with expert knowledge**.

A successful implementation requires:

- **AI-based analysis of regulatory texts** – Automating the extraction and classification of regulatory obligations from EU legal texts to enable real-time burden assessment.
- **Heuristics and metrics** – Translating regulatory burden expertise into quantifiable rules and indicators that allow structured comparison of different regulations.
- **Pilot testing on all levels of (EU) legislation** – Validating the index by applying it to legal act texts to ensure practical applicability and refine measurement accuracy.
- **Integration into the EU and Member States policymaking process** – Embedding the RBI in Impact Assessments and Regulatory Fitness Checks (REFIT) to provide structured, data-driven insights on regulatory burdens before legislation is enacted.

The EU's **ambition** for Europe to become the most dynamic and competitive knowledge-based economy in the world. However, regulatory complexity and administrative burdens continue to hinder innovation, investment, and growth, particularly for SMEs. The Regulatory Burden Index represents a possible **next step in realizing the EU ambition by making regulatory policymaking more innovative, transparent, data-driven, and business-friendly**. It is therefore recommended that this AI tool be developed at the EU level and made available for use by all Member States.

### B. The SME Indicator Company Approach: a targeted and measurable strategy for reducing regulatory burden

The SME Indicator Company approach offers a **targeted and efficient** method to assess and reduce regulatory burdens by analysing the impact of EU regulations on representative businesses within key sectors. Rather than conducting impractical large-scale baseline measurements, this method examines **sector-specific regulatory burdens** and **differences in national implementation** by hypothetically placing indicator companies across selected Member States. This allows for **comparative insights**, identifying best practices and inefficiencies in regulation.

To ensure measurable and impactful burden reduction, a **reduction target of 20-25% per indicator company** is proposed, with a **baseline set as of July 1, 2025**. This enables the development of concrete reduction proposals, aligned with the Standard Cost Model principles. Additionally, **increases in**

**regulatory burdens** should also be quantified at the indicator company level and offset to maintain a **net reduction target**.

By systematically applying this approach, **effective burden reduction programs** can be developed, ensuring that improvements for indicator companies benefit **a wide range of SMEs**. AI tools can further enhance this analysis by mapping regulatory overlaps and inconsistencies, while aligning **ex-post evaluations** with **ex-ante assessments** to create a **cohesive, data-driven regulatory framework**.

To accelerate implementation, a **structural use of an Omnibus approach** is essential. This allows for interim regulatory adjustments without waiting for lengthy evaluation cycles, ensuring that **SMEs experience tangible relief in a timely manner**.

### **C. Evidence-informed legislative Development for a predictable and business-friendly EU Regulatory Framework**

To mitigate the uncertainty and cumulative burdens caused by the rapid introduction of new EU legislation, particularly in the green and digital transitions, a more **evidence-informed legislative process** is essential. New regulations should only take **full effect once all obligations and implementation plans** are clearly defined at the operational level.

#### **Key Elements of an adaptive approach:**

- Thorough cumulative burden analysis should be conducted to prevent regulatory overlap and inconsistencies, ensuring alignment with business processes, data flows, and EU standards.
- AI-driven risk assessments can help predict regulatory burdens (trickle-down effect) and propose alternative solutions to minimize regulatory burden.
- Interim facilitative measures such as development programs and subsidies should support businesses, particularly SMEs, by allowing them to co-develop and test implementation strategies in collaboration with frontrunner companies across Member States.
- Stricter simultaneous implementation across all Member States should be mandatory to ensure a level playing field, avoiding fragmented enforcement and competitive disadvantages.

By embedding **clarity, alignment, and technological support** into the legislative process, this approach will foster **predictable, business-friendly regulations**, reducing unnecessary burdens and strengthening SME competitiveness across the EU. A similar approach has already been applied in the development of the Carbon Border Adjustment Mechanism (CBAM).

### **D. Strengthening uniform implementation for a competitive EU**

Inconsistent implementation of EU legislation undermines the level playing field, hindering competitiveness and productivity. To address this, **greater use of regulations instead of directives** is recommended where full harmonization is justified, while allowing flexibility where needed.

To achieve this, greater use of regulations rather than directives is recommended where maximum harmonization is justified, minimizing implementation differences between Member States. In some cases, more freedom is needed for Member States (such as for the Nature Restoration Regulation, which should have been a directive due to widely diverging situations in Member States) and in some cases more harmonisation (such as for the CSDDD, which should have been a Regulation). The essence is

that the legislator should carefully consider what instrument is the right approach in a specific case. And this should not only be a political argumentation.

**To prevent market fragmentation**, the EU should:

- Use the principle of "One EU Rule In, 27 National Rules Out" – EU regulations should replace national laws when full harmonization is justified to ensure uniform application and eliminate divergent national implementations.
- Monitoring and Promoting Best Practices – The EU should track, compare, and promote the most efficient regulatory practices across Member States, ensuring consistent and effective implementation.

Additionally, an enforcement mechanism should ensure compliance with reduction targets and harmonization efforts. If Member States fail to implement regulations uniformly, **mutual recognition** should apply: **compliance in one Member State should automatically be recognized in all others**. This incentivizes transparent, efficient regulation and reduces barriers for businesses.

By embedding these principles into EU policymaking, regulatory burdens can be significantly reduced, fostering a predictable, business-friendly regulatory environment that strengthens competitiveness and the Single Market.

## Comparison of "A Simpler and Faster Europe" and "A Business-Centric Approach to Cutting Red Tape"

In response to growing concerns over regulatory burdens, both A Simpler and Faster Europe<sup>1</sup> (European Commission) and A Business-Centric Approach to Cutting Red Tape (European Economic and Social Committee) were developed in the same period, reflecting a shared urgency to address regulatory burden and its impact on European businesses. **Both reports recognize the pressing need to reduce regulatory burdens and improve the efficiency of EU legislation.** They stress that excessive administrative complexity hinders investment, innovation, and competitiveness. Both share common goals: enhancing the implementation of EU legislation, preventing regulatory fragmentation across Member States, and ensuring that new regulations are clear, predictable, and proportionate. They also emphasize the importance of digitalization, AI, and structured simplification efforts, including the reduction of reporting obligations and better coordination with national authorities.

### Diverging Approaches: Process vs. Systematic Reform

However, the reports differ in their approach. A Simpler and Faster Europe primarily focuses on administrative streamlining through initiatives like Omnibus simplification packages, a 25% reduction in reporting obligations (35% for SMEs), and increased collaboration with Member States. Its approach is process-oriented, aiming to accelerate legislative simplification through incremental improvements. **However, it assumes that reducing obligations at the EU level will automatically translate into tangible reductions at the national level.** This overlooks a key challenge: for many directives, Member States have implemented national laws that would require separate revisions to reflect EU-level simplifications. The report does not fully address how the Commission's proposed measures will materialize for businesses if national regulatory frameworks or implementation (incl. supervision and enforcement by legal courts) remain unchanged.

### A Business-Centric, Data-Driven Approach to Cutting Red Tape

In contrast, A Business-Centric Approach to Cutting Red Tape takes a systematic, data-driven approach, introducing the Regulatory Burden Index (RBI): an AI-powered tool to quantify and benchmark regulatory burdens across the EU. It explicitly acknowledges the complexity of regulatory layers and the role of national implementation, emphasizing **that real burden reduction must be measured from the perspective of the entrepreneur.** The report proposes binding enforcement mechanisms to ensure compliance with reduction targets, drawing from successful national models and approaches. It also advocates for structural legislative reform, ensuring **that new laws take effect only when all implementation obligations are clearly defined**, thereby preventing the regulatory uncertainty that businesses frequently encounter.

### Conclusion

Both reports offer complementary strategies. However, **A Simpler and Faster Europe risks overestimating the direct impact of EU-level reductions** by assuming that regulatory simplifications will automatically translate to national implementation. **A Business-Centric Approach to Cutting Red Tape, by contrast, places the entrepreneur at the centre and calls for a systematic, measurable, and enforceable approach to reducing regulatory burdens at all levels of governance.**

A truly effective EU strategy should integrate the pragmatic implementation focus of A Simpler and Faster Europe with the business-centred, data-driven methodology of Cutting Red Tape to deliver real and lasting regulatory improvement.

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<sup>1</sup> European Commission, A simpler and faster Europe: Communication on implementation and simplification, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the regions. Strasbourg, 11.2.2025



## **1. Introduction**

In the light of international developments, there is an urgent need for the EU to strengthen its competitive position in the global economy, focusing on growth, innovation, and prosperity. However, these ambitions are hampered by an increasing regulatory burden arising from a complex and extensive array of new legislation. Compliance costs are a significant challenge, particularly for small and medium-sized enterprises (SMEs), which form the backbone of the European economy but face constrained growth opportunities.

Within the EU, there is a widespread sense of a sharp increase in regulatory burden, particularly in areas concerning environmental, social, and governance (ESG) regulations. This issue extends beyond heightened compliance costs, negatively affecting investment, employment, and overall economic growth. One of the key challenges is that the development and implementation of regulations involve multiple governance layers, each interpreting and applying rules in its own way.

At a minimum, five distinct layers of administrative burden can be identified: primary EU legislation, secondary legislation, transposition (which often includes gold plating<sup>2</sup>, leading to fragmentation within the single market and additional burdens for businesses), supervision of national implementation, and enforcement by legal courts. In reality, the process is even more intricate due to the influence on enforcement by regulatory bodies and supervisors.

### **Study objectives**

This study, conducted at the request of the European Economic and Social Committee (EESC), aims to:

1. **Analyse Regulatory Expansion and Competitiveness Impact:** Examine the quantitative and qualitative growth of regulatory activities by the European Commission (2019-2024) and assess their impact on European competitiveness.
2. **Evaluate and Enhance Better Regulation Tools:** Critically review the effectiveness and limitations of current better regulation initiatives and propose improvements, including real-time monitoring tools leveraging digital or AI technologies.
3. **Develop and Apply a Regulatory Burden Index:** Create an index of regulatory and bureaucracy costs, using new heuristics and metrics, to measure cumulative impacts and guide sustainable policymaking.
4. **Provide Recommendations to Reduce Complexity:** Use EU legislation as case studies to suggest practical solutions and mechanisms, like a competitiveness check, for reducing regulatory burdens and improving efficiency.

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2 <sup>2</sup> 'Gold plating' is a widely used term in the context of the implementation of the EU law, which refers to additional national obligations that go beyond EU requirements. In practical terms, it is considered as an imposition of extra requirements and administrative burden (norms, guidelines and procedures) interfering with the expected policy goals to be achieved by EU legislation. High Level Expert Group HLG\_16\_0008\_00, 16 November 2016.

## **Scope of this pilot study**

This study was conducted as a pilot, aiming to provide concrete suggestions for better managing regulatory burdens within the European Commission while exploring how AI can be leveraged in this context. The recommendations for improving regulatory control, and thereby enhancing the business climate in Europe, are grounded in insights gained by the authors over the past 20 years through extensive work in various countries. These insights were further enriched with ideas and suggestions from other stakeholders, including industry associations and companies. The study also examined how AI can support efforts to manage regulatory burdens, both by preventing unnecessary regulations and by identifying concrete solutions to reduce existing burdens.

To illustrate how EU regulation contribute to administrative burdens in different Member States, how these effects vary, and what this means for businesses, the report includes text boxes with concrete examples. In summary, this study does not represent an in-depth scientific analysis but rather offers practice-driven insights based on diverse research and methods for identifying and mitigating regulatory pressure.

## **Structure of the report**

Chapter 2 outlines the expansion of EU regulation and its impact on businesses, particularly SMEs. It examines the cumulative regulatory burden and how national interpretations and implementations of EU legislation lead to fragmentation within the Single Market. Using concrete case studies, the chapter illustrates how regulation creates administrative burdens across different Member States.

Chapter 3 then evaluates the Better Regulation Program, which aims to make EU legislation more effective and less burdensome. Despite its objectives, the program has delivered limited results. This chapter analyses why existing tools, such as impact assessments and the REFIT program, often fall short and identifies key lessons from successful national initiatives.

Chapter 4 introduces the Regulatory Burden Index, an AI-driven tool designed to systematically measure and assess regulatory burdens. The chapter explains how the index analyses legislation, enables cross-country comparisons, and helps policymakers identify unnecessary administrative costs. It also explores the role of AI in processing complex legal texts efficiently and highlights the challenges involved in implementation.

Finally, Chapter 5 presents concrete recommendations for reducing regulatory burdens in a structural and measurable way. The focus is on improving the legislative process, ensuring more uniform implementation across the EU, and leveraging technological solutions such as AI. These recommendations provide a practical roadmap towards a more predictable, business-friendly regulatory environment in the EU.

## 2. Analysis of Regulatory Expansion and Competitiveness Impact

### 2.1 Regulatory Expansion

#### Growth in EU regulation

The European Commission has undertaken various initiatives in recent years to simplify EU legislation and reduce regulatory burdens on businesses and citizens, yet the outcomes remain mixed. While the Juncker Commission achieved a notable reduction in new legislative proposals, the trend of regulatory growth has resumed under the Von der Leyen-I Commission (see figure below)<sup>3</sup>. As concluded in the Draghi report<sup>4</sup>, the stock of regulation remains large and new regulation in the EU is growing faster than in other comparable economies. E.g. between 2019 and 2024, around 3,500 laws and 2,000 resolutions were passed at the U.S. federal level, while the EU adopted approximately 13,000 acts.

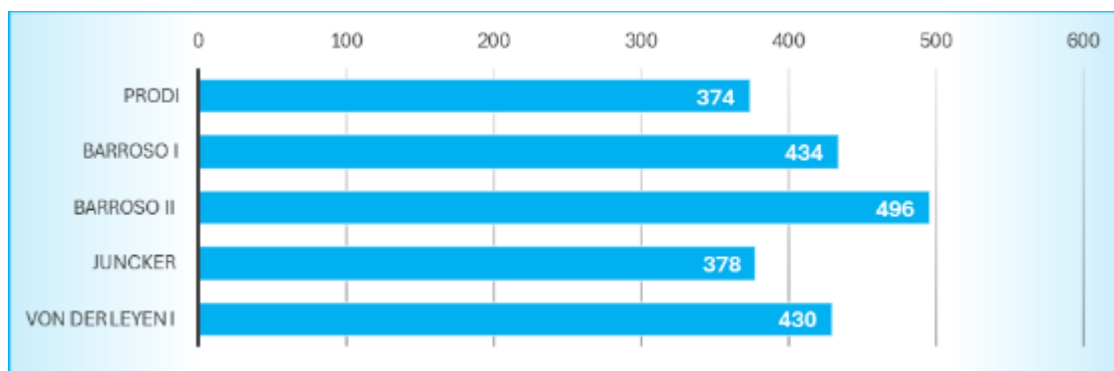


Figure 2 Number of Commission legislative proposals per five-year term [Bruegel<sup>3</sup> based on data from EUR-Lex. Da]

#### Complexity of EU regulation

The regulatory burden within the EU has not only increased due to the growing number of legislative acts but also as a result of rising regulatory complexity. This is often illustrated by the increase in the number of pages or words per law<sup>5 6</sup>. While this can serve as an indicator, it is not necessarily a measure of complexity. In some cases, more detailed provisions are essential to enhance clarity and applicability, ultimately facilitating compliance for businesses and institutions.

From the perspective of businesses<sup>7</sup>, the increasing complexity of regulation is primarily driven by three underlying factors:

- 3 Breugel (23 September 2024), Simplifying EU law: a cumbersome task with mixed results, The volume and complexity of EU laws continue to increase despite measures taken in previous mandates to make existing legislation less burdensome. K. Sekut and J.S. Marcus.
- 4 European Commission (September 2024) The future of European competitiveness Part A | A competitiveness strategy for Europe.
- 5 Between 2017 and 2022, the European legislator has passed a total of 850 new obligations directed towards companies, contained in 36 directives and 80 regulations representing 5 422 pages of legislation. Source MEDEF
- 6 MEDEF Mouvement des Entreprises de France (March 2023) New obligations imposed by European regulations on companies between 2017 and 2022
- 7 These factors emerged from various discussions conducted by Sira Consulting with businesses and were further validated through interviews with industry organizations carried out as part of this study.

1. Vague and abstract formulation. EU legislation, partly due to the necessity of political compromises, is often drafted in broad and abstract terms. This makes it difficult for businesses to determine its concrete implications for their operations. The practical implementation details are typically developed later through secondary legislation, while the main legislation is already in force. This forces business to sort out how to implement legislation without the necessary guidance by the Commission, leading to uncertainty and delays in business adaptation.
2. Diverging national implementation. The general nature of EU legislation allows Member States (or national and local bodies) to interpret and implement details in different ways. This results in a fragmented and complex regulatory landscape, where businesses face varying and sometimes contradictory obligations depending on the Member State in which they operate. Equally, up to 27 Member State implementation legislation may be applicable to the same value chain. As a result, cross-border activities within the Single Market are unnecessarily constrained.
3. Lack of alignment with existing regulation. New legislation is often developed without sufficient coordination with existing requirements or simultaneously introduced new legislation. Policymakers focus primarily on achieving new policy objectives without systematically considering the regulatory framework that businesses are already subject to. This leads to overlapping, duplicative, and sometimes contradictory requirements, further increasing the cumulative regulatory burden and compliance costs for businesses. Consequently, there is no level playing field within Europe for complying with EU obligations.

To address these challenges and achieve a meaningful reduction in regulatory burdens within the EU, an integrated approach is required. The reports by Draghi<sup>8</sup> and Letta<sup>9</sup> emphasize the need for a coherent strategy in which regulations are not only assessed individually but also evaluated in relation to the broader regulatory framework and the operational realities of European businesses.

## **2.2 Cumulative Regulatory Burden: hampering business growth**

Companies experience regulatory burden not only due to the requirements of individual legal obligations but, more importantly, due to the accumulation of multiple legal acts over time. When addressing regulatory reduction, policymakers often focus on the impact of a single law. In reality, however, businesses must simultaneously comply with a wide range of requirements in areas such as environmental protection, labor law, taxation, product safety, and reporting.

New regulation is continuously added to this framework, forcing businesses to make ongoing adjustments, leading to additional costs, administrative burdens, and uncertainty. It is this cumulative regulatory burden, the combined weight of existing and new obligations, that places the greatest strain on businesses, limiting their productivity and capacity for innovation.

In addition, there are some unintended side effects. Larger companies can push down regulatory burden compliance in their supply chain to be compliant (e.g. these so called ‘indirect costs’ were one of the critical review points in the EU impact assessment of the Corporate Sustainability Reporting Directive CSRD, see case 2). In doing so (en)forcing regulation upon SME’s as a “License to Operate” or knock-

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<sup>8</sup> European Commission (September 2024) The future of European competitiveness Part A | A competitiveness strategy for Europe

<sup>9</sup> Enrico Letta (2024) Much More than a market, Empowering the Single Market to deliver a sustainable future

out to remain a supplier. This is raising the bar (and cost) and will favour companies that have the critical mass and means to maintain the staff and systems required to be compliant.

The result of this growth in number of regulations and complexity is that regulation is seen by more than 60% of EU companies as an obstacle to investment, with 55% of SMEs flagging regulatory obstacles and the administrative burden as their greatest challenge. On the level of Member States these figures can be significantly higher<sup>10</sup>.

### The Impact of Implementation Peaks

New legal acts rarely take effect simultaneously. Each legislative package has its own implementation date, requiring businesses to continuously invest in adapting their processes, systems, and workflows. This results in:

- High short-term implementation costs: Businesses must allocate time and resources for regulatory analysis, training, and process adjustments.
- Ongoing long-term compliance costs: Even after implementation, companies face continued expenses related to reporting, monitoring, and audits.

These temporary cost and workload peaks accumulate over time, particularly in sectors subject to frequent regulatory changes (see figure below). This necessitates a strategic approach from businesses to manage peak compliance burdens effectively.

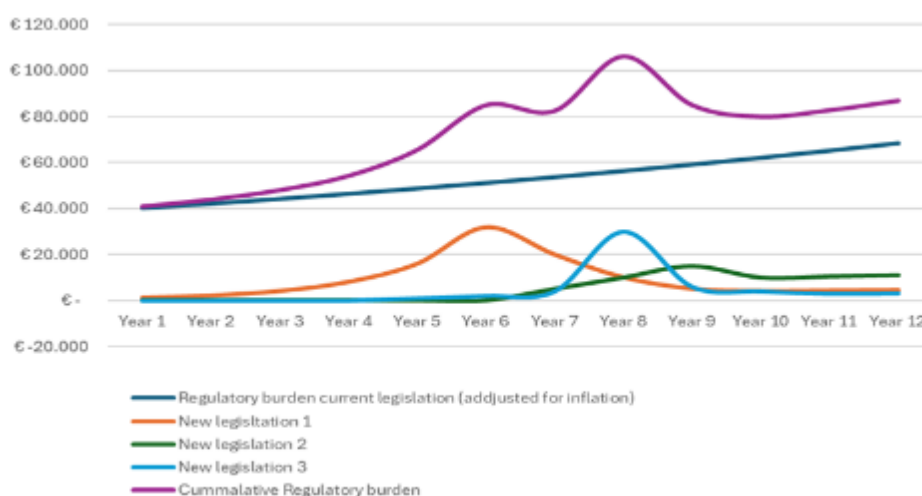


Figure 3 Cumulative Regulatory burden including implementation peaks<sup>11</sup>

Businesses employ various strategies to manage implementation peaks. Some choose to hire external support, which can alleviate workload pressures but also leads to higher costs and places additional strain on financial resources. Others opt to reallocate internal capacity, temporarily diverting employees from their core responsibilities. While this approach can help distribute the burden, it comes at the expense of productivity and shifts focus away from essential business activities.

Regardless of the approach taken, every hour dedicated to regulatory compliance is an hour that cannot be spent on product development, market expansion, or innovation. This dynamic ultimately hampers

<sup>10</sup> EIB European Investment Bank (2023) EIB Report to the EC on Investment Barriers 2023.

<sup>11</sup> Sira Consulting (2013) The Cost driven Approach to Regulatory burdens (CAR), Peter Bex, Sira Consulting, March 2013.

business growth and reduces competitiveness. Small and medium-sized enterprises (SMEs) are particularly affected, as they have fewer resources and limited flexibility to efficiently absorb these compliance peaks.

## **2.3 Understanding Regulatory Burden for Businesses**

To assess the impact of cumulative regulatory burden on individual businesses, a series of studies was conducted focusing on indicator companies in key sectors in the Netherlands<sup>12</sup> (see also figure 5) and Germany<sup>13</sup>. Nearly 100 companies were examined to understand how regulatory obligations accumulate over time and how businesses experience this burden in practice. Rather than isolating the impact of individual laws, the research adopts a holistic approach, analysing the entire regulatory framework that companies must navigate. This includes interactions and overlaps between different legal requirements, providing detailed insights into when and how regulatory obligations contribute to compliance costs and the organisational challenges to comply. This methodology offers a comprehensive understanding of the structural drivers behind regulatory burden and highlights critical pressure points for businesses.

From the perspective of entrepreneurs, regulatory burden is viewed from two key angles. On the one hand, there are the compliance costs. This includes the time investment and external expenses that businesses must undertake to implement and maintain compliance. On the other hand, there is the practical feasibility of meeting these obligations in the day-to-day operations of the business.

### **Regulatory costs**

Regulatory costs are assessed using the EU Standard Cost Model (SCM), as outlined in the Better Regulation Toolbox (measure #58). These compliance costs are categorized into administrative and adjustment costs. Administrative costs encompass the expenses associated with collecting, processing, and reporting information required by legislation. These costs are further divided into business-as-usual (BAU) costs, which refer to activities that businesses would undertake even in the absence of a legal requirement, and administrative burdens, which arise solely due to legal obligations. In the indicator company project the regulatory burden is calculated in euro's per obligation per year.

Adjustment costs, on the other hand, stem from the need to comply with substantive regulatory requirements. These include the costs associated with familiarising businesses with new regulations, acquiring new equipment or software, and hiring external consultants to ensure compliance. To obtain a comprehensive view of the total regulatory burden, these (one-off) adjustment costs need to be incorporated in the regulatory costs.

### **Workability**

Workability measures the extent to which regulatory obligations align with the operational reality of businesses. It assesses how effectively and efficiently an obligation can be implemented within existing processes. Unlike regulatory costs, which focuses on the quantifiable financial and time investments

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12 Ministry of Economic Affairs Netherlands, Sira Consulting (2022). Regulatory Burden Analysis for SME Indicator Companies: Sectoral Assessment and Cross-Sectoral Insights. Research conducted across six SME sectors: retail craft (hair salons), hospitality (hotels), retail (fashion stores), metal industry (machinery and equipment manufacturing), construction (contractors), and food industry (processed meats). The simultaneous execution of these studies provided both sector-specific and cross-sectoral insights into regulatory burden. <https://www.regeldrukmonitor.nl/mkb-indicatorbedrijven>.

13 DIHK, Sira Consulting (march 2022). Bürokratiebelastung für Unternehmen bremsen, Eine Studie am Beispiel Gastgewerbe. Peter Bex Sira Consulting, Ulrike Beland DIHK.

required for compliance, workability examines qualitative aspects that influence the ease or complexity of regulatory adherence.

1. **Clarity of Obligations:** The extent to which requirements are clearly defined and free of ambiguities. Unclear obligations lead to confusion, increase the perceived regulatory burden, and often force businesses, particularly SMEs, to rely on costly external consultants. This dependency is an additional burden, as many SMEs lack the internal expertise to navigate complex rules. A clear example is privacy regulation, which small businesses frequently struggle to understand and implement without external assistance. An other example is given in case 1 that shows that the complexity and strict enforcement of Regulation (EU) 2018/848 on Organic Production and Labelling of Organic Products impacts SME's and policy goals.
2. **Fit with Business Operations:** The degree to which an obligation integrates seamlessly into existing processes. Requirements that necessitate significant operational changes or the establishment of entirely new procedures are considered less workable. Misalignment can also impact competitiveness, particularly when compliance costs differ between businesses. EU-based companies may face higher compliance costs than their non-EU competitors, but even within the EU, differences in national implementation of the same regulations can create disparities. Companies in some Member States may encounter stricter interpretations or additional national requirements (gold-plating), putting them at a disadvantage compared to those operating under a less elaborate implementation elsewhere in the Single Market. These inconsistencies result in unequal compliance costs, complicating cross-border competition.
3. **Support and Resources Available:** The availability of guidance, tools, or external resources to assist businesses in achieving compliance. While regulatory adherence is often perceived as just a formal obligation, many businesses are also intrinsically motivated to contribute to societal objectives, such as sustainability or data protection. Regulations that provide clear and accessible pathways for companies to engage in these objectives are generally seen as more legitimate and workable.
4. **Enforcement Practices and Government Support:** The consistency and predictability of enforcement activities play a crucial role in regulatory workability. Fair and transparent enforcement enhances compliance, while unpredictable or inconsistent enforcement creates uncertainty. Additionally, the efficiency and responsiveness of government services significantly affect the perceived feasibility of regulatory requirements. Businesses highly value swift and effective support from public authorities. However, slow response times and a lack of direct assistance often push businesses toward costly external consultants. When government agencies refer companies to external consultants rather than offering direct guidance, this further exacerbates the perceived regulatory burden.

Workability does not assess whether businesses support a regulatory obligation or consider it desirable; it strictly evaluates the practical feasibility of compliance. The question of whether an obligation is necessary or justified is a political and administrative consideration, separate from the assessment of regulatory burden. In practice, businesses often acknowledge the legitimacy of the policy objectives underlying regulations but find the associated requirements too costly or impractical. This highlights a shared interest between policymakers and businesses: ensuring that regulations effectively achieve their intended goals without imposing unnecessary complexity or inefficiencies.



## Case 1. Strict enforcement of production and labelling of organic products

The main EU legislation on organic products is Regulation (EU) 2018/848.<sup>1</sup> The rules apply to all organic products, including agricultural products, processed foods, animal feed, and seeds. Businesses involved in food preparation, trade/import, organic retail, online sales, livestock farming, or crop cultivation must comply. Key aspects include:

- Production rules: Restrictions on chemical pesticides and fertilizers, animal welfare standards, and avoidance of genetically modified organisms (GMOs).
- Certification and control: Strict control systems within the EU and for imported organic products. Small farmers can be certified collectively to reduce costs.
- Labelling: Products must meet specific criteria to bear the EU organic logo.
- Import regulations: New requirements for organic products from outside the EU to ensure compliance with equivalent standards.

National and private bodies oversee certification and control. Some Member States use a Certification and Accreditation System for Agricultural Products (SKAL) to regulate the certification and accreditation of agricultural products, including organic products. In the Netherlands, certification is carried out by 'SKAL Biocontrol', a foundation that monitors compliance with EU organic farming regulations. Businesses must undergo thorough preparation, including an admission assessment and a complete business plan. Upon certification, they may use the EU organic label on food, pet food, plants, or flower bulbs. In 2023, SKAL conducted 9,354 inspections, of which 524 inspections at high-risk businesses.<sup>2</sup> A notable difference with Germany is that Germany allows lower inspection frequencies for low-risk businesses.<sup>5</sup>

### Impact

The certification requirement for organic products imposes high regulatory pressure and disproportionate compliance costs, especially for small businesses. A 2019 audit by the European Commission<sup>3</sup> found that the Netherlands failed to adequately verify whether exempted businesses met the exemption criteria. In response, SKAL introduced new controls and tightened existing ones, resulting in a number of consequences for companies.<sup>4</sup> In 2024, the Dutch Advisory Board on Regulatory Burden (ATR) has raised concerns, based on research findings:<sup>4</sup>

- Initial certification costs for a retail outlet range from €1,000 to €4,000, with annual recurring costs between €5,000 and €15,000.
- Businesses must maintain a *mass balance*, meaning they must record purchases and sales in kilograms, even for products sold per piece. For some businesses, this is unfeasible.
- Strict physical separation requirements for storage, transport, and distribution result in layered inspections and high investment costs, particularly for small retailers. This rule prevents non-organic products from being sold as organic within the supply chain.
- Exemptions from certification for small mixed retailers still cause regulatory burden due to the registration and checks needed to ensure compliance with exemption conditions.
- Businesses selling only a small portion of organic products face the greatest impact, leading to reduced availability of organic products and increased use of extra packaging materials.



ATR notes that the regulatory burden of these EU rules was not adequately assessed in advance, even in the Impact Assessment.<sup>4</sup> The EU legislator aimed to eliminate fraud risks in organic products, leading to extensive controls and requirements. This layering of regulations creates high costs and impractical conditions for businesses. Additionally, ATR warns that organic product requirements are too strict, potentially leading to: fewer businesses selling organic products; businesses opting not to use the ‘organic’ label; a shift to selling only pre-packaged organic products, or the use of alternative, non-protected labels.<sup>5</sup>

### Improvements

ATR advises the Ministry of Agriculture, Fisheries, Food Security and Nature (LVVN) to assess costs and engage more with businesses before implementing new rules.<sup>4</sup> Reducing compliance costs through adjustments to EU regulations should also be considered. ATR suggests additional measures, such as less frequent inspections for low-risk businesses and increased support from SKAL and industry associations for certification applications.

1. <https://eur-lex.europa.eu/legal-content/nl/TXT/?uri=CELEX%3A32018R0848>
2. [www.skal.nl/assets/uploads/Skal-Jaarverslag-2023\\_DEF.pdf](http://www.skal.nl/assets/uploads/Skal-Jaarverslag-2023_DEF.pdf)
3. DG (SANTE) 2019-6712 nr. 28 and 29.
4. ATR (2024). Recommendation to Reduce Regulatory Burden of Certification Requirement for Organic Product Retailers. [www.adviescollegegeldruk.nl/documenten/adviezen/2024/01/18/atr-advies-verminderen-regeldruk-certificeringsplicht-verkooppunten-biologische-producten](http://www.adviescollegegeldruk.nl/documenten/adviezen/2024/01/18/atr-advies-verminderen-regeldruk-certificeringsplicht-verkooppunten-biologische-producten)
5. <https://panteia.nl/actueel/nieuws/regeldruk-certificering-verkoop-biologische-producten/>; [www.adviescollegegeldruk.nl/documenten/rapporten/2022/06/01/panteia-quickscan-regeldruk-verkoop-biologische-producten](http://www.adviescollegegeldruk.nl/documenten/rapporten/2022/06/01/panteia-quickscan-regeldruk-verkoop-biologische-producten)

### Analysis of Regulatory Costs vs. Workability

An analysis of regulatory burden among SME indicator companies<sup>14</sup> demonstrates that regulatory costs alone do not determine the full impact of regulations; workability within business operations is equally crucial. To visualise this relationship, a regulatory burden matrix has been used, assessing legal obligations along two dimensions: costs and workability. This approach clarifies which obligations generate the highest perceived burden and where policy interventions can be most effective in reducing regulatory pressure while enhancing economic efficiency (see figure below).

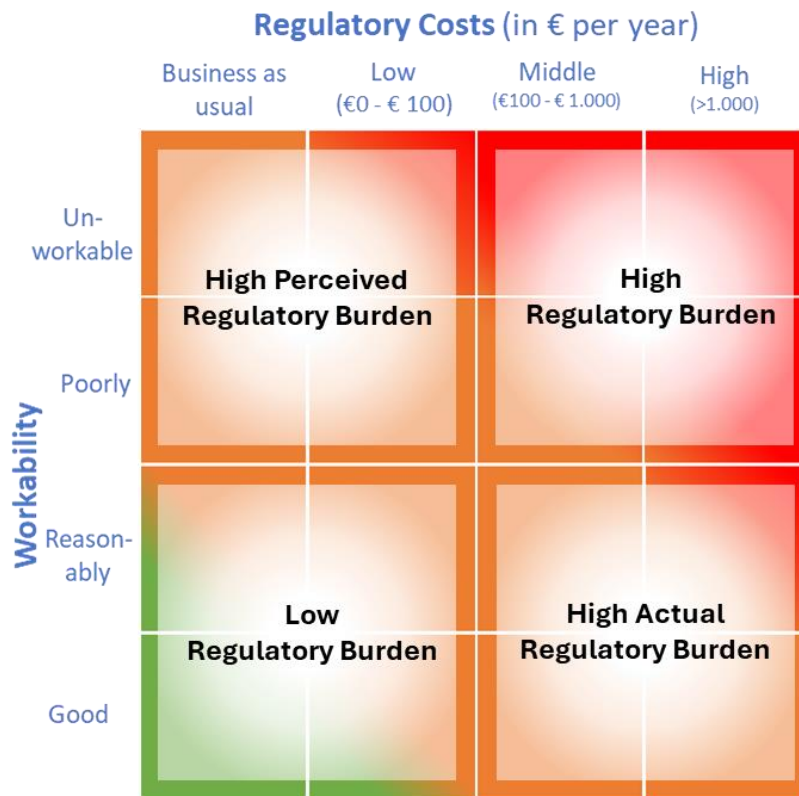


Figure 3 Four Categories of Regulatory Burden

The four quadrants of the matrix represent distinct categories of regulatory burden, each reflecting a different combination of regulatory costs and workability. The following sections provide a detailed explanation of each quadrant, highlighting their implications for businesses and potential areas for policy intervention.

- **High Regulatory Burden (High Cost, Low Workability).** These obligations are both expensive and difficult to implement, leading to a high level of both perceived and actual regulatory pressure. Such requirements often force businesses to allocate significant resources to compliance rather than growth and innovation. This category is particularly detrimental to competitiveness, as excessive regulatory costs can disproportionately impact SMEs, reducing their ability to invest in productivity-enhancing activities.
- **High Actual Regulatory Burden (High Cost, High Workability).** While these obligations involve significant costs, they align well with existing business processes. Lowering regulatory costs in this category would primarily yield economic benefits, such as increased profitability and investment capacity. Businesses that can efficiently integrate these regulations may still remain competitive, but high compliance expenditures can limit their ability to allocate funds to research, development, and scaling operations.
- **High Perceived Regulatory Burden (Low Cost, Low Workability).** The direct financial costs of these obligations are limited, but implementation is complex or unclear. This creates frustration among entrepreneurs, who frequently need to seek external assistance, adding indirect costs. In turn, this diverts managerial attention from core business activities, reducing overall efficiency and innovation potential. Streamlining regulatory clarity in this category, such as through clearer guidelines and simplified compliance processes, can significantly enhance productivity without major budgetary implications.

- **Low Regulatory Burden (Low Cost, High Workability).** These obligations integrate seamlessly into business operations and, in some cases, would be carried out even in the absence of legal mandates. For example, wage payments and product price disclosures are essential business practices independent of regulation. Regulations in this category generally have minimal impact on competitiveness and productivity, as they do not impose significant additional constraints.

## **2.4 Concluding remarks**

### **Assess the cumulative impact to address regulatory burdens**

Effectively addressing regulatory burden requires a fundamental shift in perspective: one that moves beyond assessing individual regulations in isolation and instead considers their cumulative impact on businesses. As this analysis has shown, the sheer volume and complexity of EU regulation has continued to grow, often leading to overlapping, inconsistent, and administratively heavy compliance obligations. While each regulation may serve a distinct policy objective, the combined effect on businesses is often far greater than the sum of its parts.

To fully understand the impact of regulatory burden, it is essential to adopt the perspective of entrepreneurs themselves. Businesses do not experience regulations as isolated requirements but as an interconnected and evolving framework that shapes their operational reality. SME's, in particular, struggle with fragmented implementation, high compliance peaks, and a lack of clear guidance, all of which divert resources away from growth, innovation, and competitiveness<sup>15</sup>.

A more effective approach to regulatory reform must therefore move beyond incremental adjustments to individual rules and instead focus on reducing the overall regulatory load. Learning from the SME Indicator Company approach (see figure 4), this requires a holistic view of the total burden placed on businesses, ensuring that simplification efforts are not merely symbolic but lead to tangible improvements in workability and compliance efficiency. Without this broader oversight, there is a risk that well-intended reforms fail to alleviate the true challenges businesses face.

By systematically identifying where regulations intersect, overlap, and create unintended bottlenecks, policymakers can develop targeted solutions that reduce unnecessary burdens while maintaining regulatory objectives. This approach will not only enhance regulatory efficiency but also unlock business potential, drive innovation, and strengthen Europe's long-term competitiveness. In short, to truly cut red tape, we must first see it through the eyes of those who navigate it daily.

And just to be clear, business needs rules and actively ask for and proposes rules. The problem is regulatory burdens caused by rules which are not well designed. The issue is not regulations per se, but regulatory quality and the approach. The fact that laws are drafted for a small number of entities with exemptions for the majority. Instead, the EU should apply the 'think-small-first principle', adopting different conditions for large entities and not the other way around.



### CONCLUSIONS



SMEs suffer regulatory burden, even more than larger companies



80% of obligations is direct or indirect influenced by EU regulations



Regulatory burden increase when they have to depend on third parties



30% - 50% of obligations cause no significant regulatory burden

Figure 4 Summary Dutch study SME Indicator Companies

### 3. Evaluation of Better Regulation Tools

#### 3.1 Better Regulation Program

The Better Regulation program of the European Commission is designed to develop and implement policies and legislation that are effective, efficient, and future-proof. Its core principles include transparency, evidence-based decision-making, and stakeholder engagement. The program aims to improve and simplify legislation, ensuring that it better aligns with the needs of citizens, businesses, and governments across the EU. It operates under the principles of subsidiarity and proportionality, meaning that regulations are introduced at the EU level only when strictly necessary.

The proportionality principle focuses on the financial and administrative impact of proposed legislation, to ensure that regulatory actions do not exceed what is necessary to achieve the legislative and policy objectives. Any such impact must be minimised and must be proportionate to the policy objectives. This means that all policies are delivered in the simplest and least costly way, avoiding unnecessary red tape.

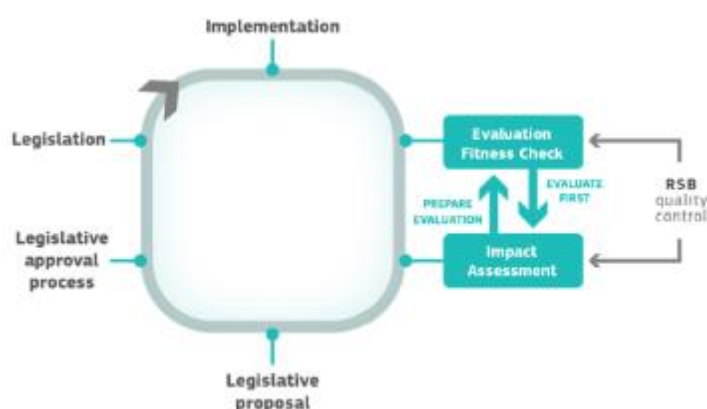


Figure 5 EU Policy Cycle<sup>16</sup>

Consulting stakeholders is at the heart of the Better Regulation agenda. Stakeholders such as businesses, citizens and sector organisations can share their views and evidence on proposals of new EU policies, legal acts and existing laws (evaluations and fitness checks). They can provide input through the "Have Your Say" portal, Calls for Evidence, and Public Consultations, ensuring their perspectives contribute to the development and evaluation of EU policies and legislation<sup>17</sup>.

The 'Have Your Say' platform enables stakeholders to share their views and provide evidence on proposed EU policies, legal acts, and existing regulations, including evaluations and fitness checks. The Calls for Evidence are open for four weeks and allow stakeholders to provide input on impact assessments, evaluations, and fitness checks. The Public Consultations are open for twelve weeks, these consultations focus on legislative proposals, allowing a broader range of stakeholders to contribute views before final decisions are made.

The Better Regulation Guidelines<sup>18</sup> and Toolbox provides a comprehensive set of guidelines and methodological tools to support policymakers in the design, evaluation, and improvement of legislation.

<sup>16</sup> [Better regulation - European Commission](#)

<sup>17</sup> European Commission (April 2019), Better regulation, Taking stock and sustaining our commitment#EUHaveYourSay

<sup>18</sup> European Commission (November 2021) Better Regulation Guidelines SWD(2021)305 Final

By offering practical instruments, the toolbox facilitates the effective implementation of the Better Regulation agenda, ensuring that EU regulations are both impactful and proportionate.

Aligning with the view that addressing the growing regulatory burden requires a stronger entrepreneurial perspective, the Better Regulation program can be analysed from two key angles while acknowledging that this distinction is not always perfectly clear-cut. The first focuses primarily on limiting the regulatory burden impact of new legislation. The second concentrates on reducing the regulatory burden of existing regulations. Assessing the program through these two lenses provides deeper insight into how regulatory frameworks can be optimised to support businesses while maintaining their intended policy objectives.

### **New legislation: Impact Assessment**

Several instruments from the Better Regulation Toolbox play a crucial role in reducing regulatory burden in new EU legislation. These tools are designed to ensure that regulations remain efficient, proportionate, and practical, particularly for businesses and SMEs.

One of the most significant instruments is the Impact Assessment, a comprehensive evaluation of the economic, social, and environmental effects of a legislative proposal. This process helps identify unnecessary burdens and considers alternative policy options. As part of this assessment, it is mandatory to evaluate the impact on SMEs and the competitiveness of businesses.

The SME Test specifically aims to minimise burdens on SMEs, allowing for exceptions or simplified compliance procedures when necessary to prevent disproportionate costs for smaller enterprises. Additionally, the Competitiveness Check assesses how new regulations affect the competitive position of EU businesses, helping to ensure that legislation does not put European companies at a disadvantage compared to their global competitors or businesses operating under less stringent regulatory frameworks.

The Regulatory Scrutiny Board, an independent body of Commission officials and experts from outside the Commission, reviews impact assessments and selected evaluations.

Although the Impact Assessment is intended to limit regulatory burden in new legislation, it has inherent limitations. The process is highly technical and time-intensive, and new legislation is often a moving target that is subject to amendments during legislative negotiations and variable implementation across Member States. As a result, initial assessments may become outdated or fail to capture the full regulatory impact.

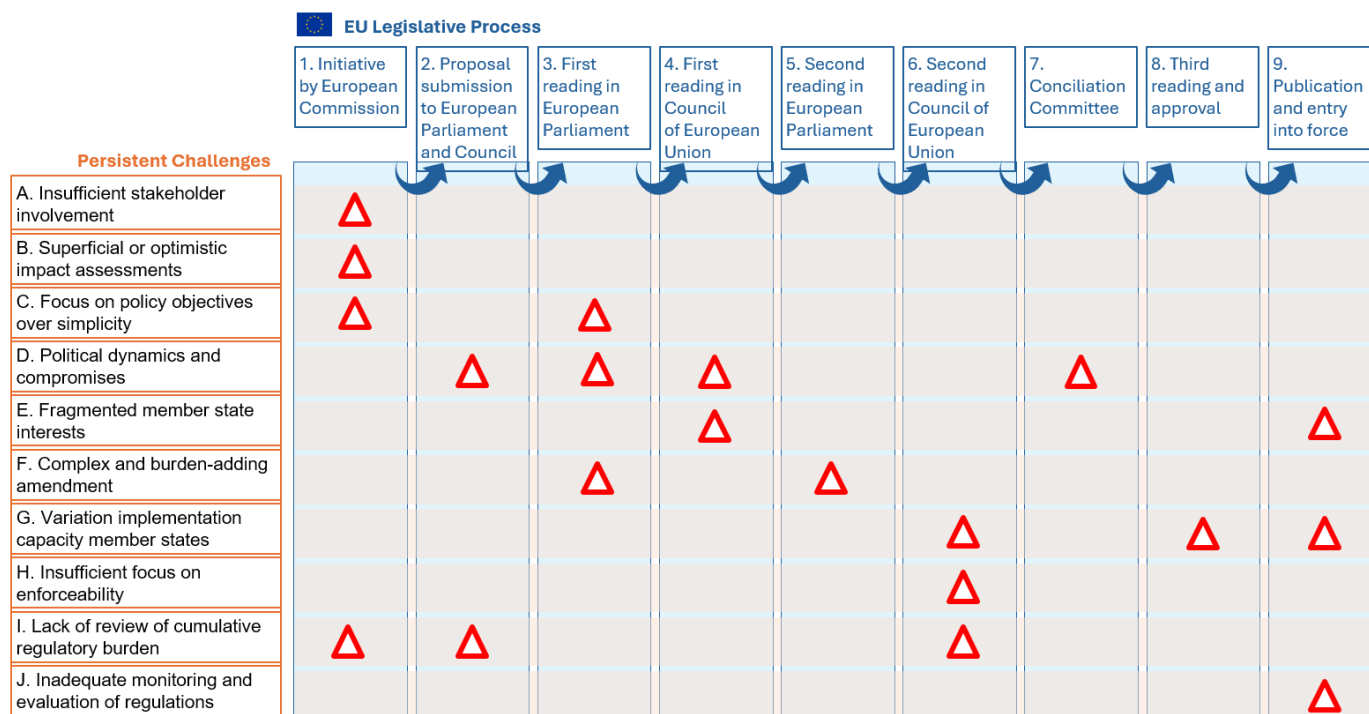
To mitigate these challenges, the Interinstitutional Agreement on Better Law-Making<sup>19</sup> was introduced to improve the efficiency and coherence of EU legislation. In this agreement, the European Commission, the European Parliament, and the Council have committed to making legislation more efficient and less burdensome. This includes encouraging the use of impact assessments for substantial amendments and promoting legislative simplification. However, in practice, challenges remain, as the Parliament and the

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Council adopts amendments without conducting thorough impact assessments<sup>20</sup>. The key bottlenecks in the legislative process, as identified in various studies<sup>21</sup>, are summarized in the textbox below.

### Textbox 1. Persistent challenges in EU Legislative Process



#### A. Insufficient stakeholder involvement

Even though consultations are held, feedback from stakeholders (especially small businesses or civil society organizations) may not be fully considered. Sometimes there is a lack of time or resources to adequately process all feedback.

#### B. Superficial or biased impact assessments

Impact assessments are designed to map the consequences of regulation, but they may be too superficial or not take into account indirect costs. Additionally, estimates of regulatory burden are often optimistic, leading to a greater burden than initially expected. In interviews it is stated that the influence of civil society organisations or companies/business organisations aiming to turn regulatory requirements into a business model, have massively increased which might have resulted in superficial or biased impact assessments.

<sup>20</sup> There have been instances where the European Parliament and the Council have conducted impact assessments for amendments or proposals to evaluate their potential consequences. A notable example is the REACH Regulation, where multiple impact assessments influenced the final design of the legislation. Similarly, during negotiations on the Water Framework Directive, impact assessments were considered to assess the implications of proposed amendments.

<sup>21</sup> European Court of Auditors (2020), Law-making in the European Union after almost 20 years of Better Regulation, Review 02, 2020



### **C. Focus on policy objectives over regulatory efficiency**

When developing proposals, the emphasis may sometimes lean too heavily on achieving policy goals—such as environmental protection or consumer rights—at the expense of regulatory efficiency. This can lead to overly complex or bureaucratic procedures.

Additionally, the Parliament often prioritizes political and societal objectives, while being less involved in the practical aspects of implementation. As a result, the implications for regulatory burden are sometimes insufficiently taken into account.

### **D. Political dynamics and compromises**

Political interests within the Parliament and the Council can lead to additional obligations to gain support, resulting in more complex legislation and compromises that increase administrative burdens. Currently, no impact assessments are conducted for amendments, but the need for a more structured approach to assessing their regulatory impact is considered.

In both the Parliament and the Council, political interests play a significant role. During the negotiation process, additional obligations may be added to gain support from certain Member States or political groups. This often leads to more complex legislation. E.g. the negotiation process between Member States can also lead to complicated arrangements that are difficult to implement and bring additional administrative burdens.

The conciliation committee's task is to reach compromises between Parliament and the Council. Also these compromises can lead to complicated provisions that are difficult to implement.

### **E. Fragmented Member State interests**

Member States often have different priorities and seek to protect national interests by introducing exceptions or specific rules. This causes fragmentation, leading to different rules for businesses in different countries.

Besides, directives must be transposed into national legislation by Member States. This can lead to differences in how rules are implemented, causing extra administrative burdens for businesses, particularly those operating across borders.

### **F. Complex and burden-adding amendment**

Members of the European Parliament can submit amendments that significantly change the original proposals, sometimes by adding specific rules for certain sectors or regions. This can lead to more exceptions and, therefore, more regulatory burden.



### **G. Variation in implementation capacity among Member States**

The Council may impose new rules that sound good in theory but are difficult to implement in certain Member States. And although legislation is approved at the EU level, there is sometimes insufficient attention to how it should be transposed into national law. Both lead to additional national rules and complexity, particularly for businesses operating across borders.

Member States often add extra requirements beyond the EU baseline. A practice known as "gold-plating." This increases regulatory complexity and administrative costs for businesses, particularly those operating in multiple countries.

### **H. Insufficient focus on enforceability**

There is not always enough consideration of how the regulation can be enforced in practice. This can result in rules that are difficult to monitor or enforce, leading to more administrative obligations for businesses to prove compliance.

### **I. Lack of review of cumulative regulatory burden**

Cumulative regulatory burden refers to the accumulated impact of multiple regulatory requirements on businesses in a certain sector, especially SMEs. Smaller enterprises, including SMEs and small mid-caps, are disproportionately affected by the regulatory environment. Although some regulations include mitigating measures for SMEs, these are often insufficient. Regulatory costs tend to weigh more heavily on these businesses due to their limited resources compared to larger firms.

The total burden of new and existing regulations is not always fully considered, leading to an accumulation of regulatory requirements.

### **J. Inadequate monitoring and evaluation of regulations**

Although the EU often prescribes evaluations of EU regulation, these may be conducted too late or insufficiently thoroughly, which means bottlenecks in implementation and administrative burdens are addressed too late. However, ex post evaluation is a valuable tool for ex ante impact assessments. Besides, the EU currently lacks a unified methodology to evaluate the cumulative regulatory impact, particularly after national implementation.

## **Evaluating and Simplifying Existing Regulations**

In addition to limiting regulatory burdens in new legislation, the European Commission employs several instruments to evaluate and simplify existing regulations.

The Regulatory Fitness and Performance Programme (REFIT) was a key initiative of the European Commission to assess and streamline existing legislation. In 2020, the REFIT platform was replaced by the Fit for Future (F4F) Platform, which operated until 2024. This platform brought together national, regional, and local authorities with stakeholders to improve and future-proof EU legislation. Following the conclusion of the F4F Platform's mandate in 2024, the Commission has continued its efforts to simplify EU law and reduce unnecessary costs, while ensuring that regulatory objectives remain intact. This includes conducting evaluations, fitness checks, and stress tests to assess and improve existing legislation.

The SOLVIT<sup>22</sup> network serves as a free mediation service, assisting businesses and citizens when national authorities misapply EU rules. By correcting implementation errors, SOLVIT helps prevent unnecessary administrative burdens and offers a faster alternative to legal proceedings, reducing the time and resources businesses must dedicate to legal disputes. Feedback from SOLVIT is also used to inform policy evaluations and impact assessments, contributing to the broader Better Regulation agenda.

Another key approach is the ‘One In, One Out’ (OIOO) principle, which aims to offset new administrative burdens by eliminating existing ones. The "One-in-One-out" (OIOO) principle introduced by the European Commission demonstrates significant potential for reducing regulatory burdens and improving the competitiveness of businesses, particularly SMEs. Early estimates indicate that the OIOO approach could generate substantial cost savings, projected at €7.3 billion annually over the next decade, contributing to a more efficient and streamlined regulatory environment. Additionally, its alignment with broader initiatives such as REFIT and the SME-test strengthens its role within the Better Regulation agenda, highlighting its ability to support sustainable and growth-oriented policymaking<sup>23</sup>.

In addition to the OIOO principle, the European Commission has set ambitious targets to reduce reporting obligations by 25% for businesses overall and 35% specifically for SMEs. These targets are designed to ease regulatory costs while ensuring that legislative objectives remain intact.

The European Commission adopted February 2025 new proposals that will cut red tape and simplify EU rules for citizens and business. In the Competitiveness Compass, the Commission set out its vision to make the EU’s economy more prosperous and competitive, building on the recommendations of the Draghi report. To regain competitiveness and unleash growth, the EU needs to foster a favourable business environment and ensure that companies can thrive. As part of the Competitiveness Compass, the EU Commission released two Omnibus packages of simplification regarding sustainability reporting and carbon border adjustment mechanisms for fairer trade (see cases 1 and 2)

In its work programme for 2025, the Commission announced a series of measures to address overlapping, unnecessary or disproportionate rules that create barriers for EU companies. Collectively, with these measures, the Commission wants to reduce administrative burdens by 25%, and by 35% for small and medium-sized businesses, by the end of its mandate in 2029.

### 3.2 Lessons learned

The OECD commends the European Union for its Better Regulation program<sup>24</sup> (BR), which focuses on transparency, evidence-based policymaking, and minimising regulatory burdens. While BR has enhanced stakeholder engagement and increased transparency, challenges remain, such as limited impact assessments<sup>25</sup>, growing complexity of legislation, and variations in national implementation<sup>26</sup>. Various organizations recommend improving consultations and impact assessments, better defining the REFIT program, and fostering national consistency in the implementation of EU legislation. Closer

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22 SOLVIT and also FIN-NET, TRIS (Technical Regulation Information System) and Your Europe empower people and businesses to fully use their rights in the single market.

23 CSES Centre for Strategy & Evaluation Services (January 2024) Application of the ‘One in, one out’ approach – and its impact on businesses, European Parliament

24 CSES Centre for Strategy & Evaluation Services (January 2024) Application of the ‘One in, one out’ approach – and its impact on businesses, European Parliament

25 Usually, Impact Assessments (IAs) are applied to proposals expected to have significant economic implications. However, it is becoming increasingly common for IAs not to be applied under the claim of urgency even when significant impacts are expected.

26 European Commission (November 2021) Better Regulation Guidelines SWD(2021)305 Final

cooperation between EU institutions and Member States is essential to achieve these objectives and strengthen businesses trust in EU policymaking<sup>27</sup>.

Despite the efforts of the BR Program and the implementation of the OIOO principle, businesses, and particularly SMEs, do not experience a noticeable reduction in regulatory burden in their daily operations. Not only due to the increasing volume of rules but also because of the way they are developed, implemented, and interpreted. Analysing the EU effort over the last decade, four issues stand out. These are often seen as technical flaws, but in essence they stem from a deeper underlying cause: the absence of strong political will to prioritise simplicity, clarity, and consistency in regulation. This lack of commitment has allowed four persistent issues in the regulatory approach to take root:

### **1. Moving target: continuous adjustments during the EU's legislative process fuels regulatory burden**

Throughout the EU legislative process, policy objectives, regulatory instruments, and legal formulations are subject to constant revisions. Consultations, (political) negotiations and amendments contribute to broadly supported legislation, and together with impact assessments this approach adds significant value to the development of legislation and enhances stakeholder participation. Nevertheless, this causes a lack of a holistic view on the final regulatory burden. Or worse, a political compromise is reached, in complete disregard of how this will work out in practice.

Additionally, interviews indicate that stakeholders who are not directly affected by regulatory burdens have a disproportionate influence on the legislative process. It also appears that Member States have limited involvement, especially in the early stages, in the development of new regulations. Several national scrutiny boards and the EU have pointed this out on multiple occasions. This further skews regulatory outcomes, often prioritizing political feasibility over practical workability, leading to unnecessary complexity and increased regulatory burden for businesses.

As a result, there is a significant risk that regulatory instruments – such as reporting obligations, external audits, and permit requirements – are introduced without fully exploring lower-burden alternatives. A clear example of this is the Impact Assessment of the Corporate Sustainability Due Diligence Directive (CSDDD), where Commission and Parliament consistently disregarded warnings on the disproportionate effects for SMEs (see case 1. Overlapping Sustainability Regulations) and possibility of voluntary approach to ESG.

### **Case 2. Overlapping Sustainability Regulations and Their Impact on Business Operations**

The Corporate Sustainability Due Diligence Directive (CSDDD), the Corporate Sustainability Reporting Directive (CSRD), and the EU Taxonomy are key pillars of the EU's sustainability regulatory framework. These regulations aim to enhance transparency, encourage responsible business practices, and guide sustainable investments. However, despite years of preparation and extensive impact assessments, their implementation has proven complex, costly, and challenging for businesses. The European Commission has now acknowledged these issues and is considering streamlining the framework to address overlapping requirements and improve feasibility.

## **Impact <sup>1</sup>**

Businesses are required to comply with multiple, interrelated obligations under these frameworks:

- CSDDD mandates that companies conduct due diligence on human rights and environmental risks throughout their supply chains.
- CSRD significantly expands corporate sustainability reporting requirements, demanding more detailed disclosures on environmental, social, and governance (ESG) factors.
- The EU Taxonomy defines which economic activities qualify as sustainable, setting strict criteria for green investments and financing.

These regulations overlap in scope, creating redundant compliance requirements and reporting complexities. Companies struggle with differing definitions, inconsistent reporting timelines, and conflicting verification processes, leading to high administrative costs and operational uncertainty. Despite extensive impact assessments, especially for CSDDD, the practical challenges of implementation were not fully anticipated, forcing regulators to reconsider the framework.

### **Unexpected Resistance from Key Stakeholders**

Adding to the complexity, accounting firms, which played a key role in developing these regulations, are now warning that businesses need more time to comply. KPMG and other major firms have called for delayed implementation for smaller businesses, citing the difficulty of aligning internal processes with the extensive new reporting obligations. This underscores a broader issue: even well-intended, thoroughly prepared regulations can lead to practical difficulties when their implementation does not align with business operations.

### **Impact on EU Competitiveness and Supply Chains**

Beyond administrative costs, these regulations affect the EU's global competitiveness. Businesses report that non-EU suppliers are reconsidering or withdrawing from trade with European firms due to the complexity of compliance requirements. Qatar, for instance, has warned that it may halt LNG exports to the EU if it faces penalties under these sustainability rules. This demonstrates how excessively rigid or unclear regulatory frameworks can have unintended economic consequences, influencing global supply chains, investment flows, and the strategic position of European companies in international markets.

### **Balancing Sustainability Goals with Feasibility**

Despite these challenges, businesses remain committed to sustainability objectives. The issue is not the ambition of the regulations themselves but rather their practical execution. Companies emphasize the need for clearer guidance, better alignment between different frameworks, and a more gradual implementation approach to ensure that compliance enhances rather than hinders sustainability efforts.

## **Improvements**

Beginning 2025 the European Commission has adopted new proposals that could cut red tape and simplify EU rules for citizens and business as part of the Competitiveness Compass<sup>2</sup>. The first two Omnibus packages<sup>3</sup> focus on streamlining sustainability reporting for large companies, easing due

diligence requirements, strengthening the carbon border adjustment mechanism, and improving access to European investment programmes. These proposals will now be reviewed by the European Parliament and the Council. However, it should be wiser to assess impacts before adopting the legislation and further correcting it. The EU has to change the approach “regulate first, correct later”.

1. Financieel Dagblad 2025, Europees plan voor samenvoegen duurzaamheidswetten verdeelt Nederlands bedrijfsleven (6 februari 2025), Frankrijk stelt voor duurzaamheidswetten drastisch te versimpelen 24 januari 2025), KPMG: Geef kleinere bedrijven meer tijd voor nieuwe duurzaamheidsregels (9 februari 2025), Qatar dreigt te stoppen met export LNG naar EU bij boetes, 22 december 2024).
2. The Competitiveness Compass, [EU competitiveness - European Commission](#)
3. Proposal for a Directive amending the Directives: Accounting, Audit, CSRD and CSDDD - Omnibus I - COM(2025)81 and Proposal postponing the application of some reporting requirements in the CSRD and the transposition deadline and application of the CSDDD - Omnibus I - COM(2025)80 – 26 February 2025

## 2. Unfinished rules: Vague legislation leads to compliance uncertainty

Due to the political decision-making process, EU legislation is often drafted in broad and abstract terms. The specifics – such as submission requirements for permits and the content of reporting obligations – are typically determined only during the implementation phase in a process of trial and error, with ongoing discussions between EU institutions, Member States, supervisors, judges and businesses caught in the middle. The outcome of this process is subsequently defined in delegated acts and guidelines, which are less subject to impact assessments or parliamentary democratic scrutiny. As a result, the practical feasibility of compliance and the actual regulatory burden often become apparent only when businesses have to implement the rules, making it difficult to proactively reduce unnecessary burdens.

A critical factor in this process is the role of public authorities and commercial advisory firms in interpreting regulations. These actors often focus on the legal and administrative aspects of regulatory compliance, rather than considering the practical business perspective. Particularly when compliance obligations create commercial opportunities for advisory firms, this can lead to excessive regulatory burdens, as outlined in the previous chapter.

### Case 3. Vague legislations leads to diverse interpretation of EU Allergen Regulation

The EU Food Information for Consumers Regulation (Regulation (EU) No 1169/2011) requires food businesses, including restaurants, to inform consumers about the presence of allergens in their dishes Article 9(1)(c). While the regulation mandates that allergen information must be clearly communicated to customers, it does not prescribe a specific format for doing so, allowing for national discretion and business-specific implementation.

#### Impact

A study on bureaucratic burden in the hospitality sector (Bürokratiebelastung für Unternehmen bremsen, Eine Studie am Beispiel Gastgewerbe) revealed that entrepreneurs interpreted this requirement in significantly different ways, leading to varying levels of perceived regulatory burden.

- **High Burden Interpretation:** Some restaurant owners understood the regulation to mean that allergens must be listed on every printed menu for each dish. For businesses with frequently changing menus, this created a significant administrative burden, as menus needed constant updates to ensure compliance.

- **Low Burden Interpretation:** Other restaurateurs adopted a more flexible approach, indicating on their menus that customers could ask staff for allergen information. This approach complied with the regulation while minimising administrative workload, resulting in little to no perceived regulatory burden for these businesses.

### **Improvements**

This case highlights the practical challenges of regulatory interpretation in the business environment. While the EU regulation itself does not explicitly require allergen listings on printed menus, ambiguity in its implementation and enforcement led to varying compliance approaches. Businesses that assumed a stricter interpretation faced significantly higher costs, while those who opted for a more flexible approach experienced minimal impact.

This divergence underscores the importance of clear implementation guidelines and proactive regulatory communication to prevent unnecessary administrative burdens. A more harmonized and explicit framework at the EU level, or clearer national guidance, could reduce regulatory uncertainty and ensure consistent application across the hospitality sector.

### **3. Patchwork of compliance: diverging rules across member states undermine the single market**

For EU directives and, to a lesser extent, regulations the Member States are responsible for national implementation. In some cases, variations in implementation exist even within individual Member States (e.g. in Germany the Bundesländer and in the Netherlands Provinces implement Birds Directive 2009/147/EG and Habitat Directive 92/43/EEG differently).

Due to varying interpretations, see also case 4, this results in a fragmented patchwork of in the worst case 27 diverging or even contradictory national rules, complicating compliance for businesses operating across borders. Instead of creating uniform legislation, this process increases administrative burdens and legal uncertainty, further undermining the predictability of the regulatory environment in the Single Market.

### **Case 4. Divergent implementation of EU obligations for the improvement of workplace safety and health**

The basis of European legislation on safety and health at work is formed by the Framework Directive (1989)<sup>1</sup> and subsequent directives focusing on specific aspects of occupational safety and health.<sup>2</sup>

Framework Directive 89/391 includes several ‘system obligations’ that are implemented in the regulations of Member States. Additional instruments are employed by Member States to promote compliance in the workplace. Member States are allowed to adopt stricter rules for the protection of workers when transposing European directives into national law. As a result, legal requirements concerning occupational safety and health may vary across different Member States. These differences can impact the effectiveness of measures aimed at improving workplace safety and health.

### **Impact**



The Belgian Ministry of Social Affairs commissioned a study on how implementation and enforcement are carried out in ten Member States.<sup>3</sup> The insights below concern two major obligations.

#### Article 9. Reporting/Registration of Workplace Accidents

The definitions of a serious accident differ between Member States. For example, in the Netherlands, a serious workplace accident is one that results in hospitalisation and/or permanent injury. In Spain, a serious accident is one that results in death, permanent or temporary incapacity, linked to specific conditions related to the event, the objects involved, and the nature of the injury.

- The Framework Directive imposes an obligation on the employer to prepare accident reports for the competent authorities. However, the directive does not explicitly require employers to investigate and analyse workplace accidents.
- In some countries, such as Italy and Denmark, employers are not required to investigate accidents.
- In the Netherlands, employers are not obligated to conduct their own investigation; however, in practice, they must examine what happened since they can be held liable for damages.
- In Belgium, the system is entirely different: the employer's prevention service must prepare a detailed report for serious accidents. Based on this report, the employer determines the necessary preventive measures and discusses them in the workplace safety committee before forwarding the report to the competent inspection authority.

#### Article 6. Risk Assessment & Evaluation (RI&E)

The Netherlands has opted to impose the RI&E obligation without exceptions on *all employers* with at least one employee. In contrast, the governments of the UK and Sweden have introduced exemptions for small businesses (smaller than five and 10 employees, respectively) regarding the written documentation of the RI&E.

When the risk analysis exceeds their own expertise, companies increasingly seek external expertise.

- In some Member States, this advice is free of charge, e.g. in Estonia and Sweden for businesses with up to 50 employees. In others, it is paid – like in France, the UK, Austria, and Denmark.
- In some Member States, employers are required to seek external advice for the RI&E, either free of charge (in Germany for businesses with up to ten employees under an alternative care system) or paid (in Belgium and Spain for businesses with 11 or more employees). In the Netherlands, companies can seek support from occupational health services and certified experts at a cost.

1. Framework Directive 98/391 <https://osha.europa.eu/en/legislation/directives/the-osh-framework-directive/the-osh-framework-directive-introduction>
2. European Directives on Occupational Safety and Health (OSH). <https://osha.europa.eu/nl/safety-and-health-legislation/european-directives>
3. Prevent (2019). European Comparison of OSH Obligations. Study on the Implementation and Enforcement of Articles 6, 7, and 9 of Framework Directive 89/391 in 10 European Countries – Comparison with the Netherlands.

#### 4. Unmeasurable targets: ambitious reduction goals without clear metrics

While the EU has set ambitious targets to reduce regulatory burdens, the lack of measurable benchmarks undermines their credibility and effectiveness. This issue is particularly evident in both the One In, One Out (OIOO) principle and the 25% and 35% reduction targets for reporting obligations.

For OIOO, there is insufficient transparency regarding the basis for calculations and how reductions are quantified. The underlying methodology remains unclear, and businesses lack access to the data used to justify the reported reductions. Furthermore, the projected savings of €7.3 billion from this program do not align with the real-world experience of entrepreneurs, raising doubts about its practical impact.

Similarly, the reporting reduction targets of 25% for businesses and 35% for SMEs, while seemingly ambitious, lack a defined baseline against which progress can be measured. Without clarity on the reference point, the reduction percentage becomes largely symbolic. Moreover, the absence of a comprehensive framework increases the risk of a selective approach, where only a limited set of reporting obligations is considered for reduction, rather than addressing the broader cumulative reporting burden faced by businesses.

### **3.3 Preconditions for an effective EU Regulatory burden reduction program**

Building on nearly 25 years of experience from Sira Consulting's work with national regulatory burden reduction programs across various countries within and beyond Europe, as well as insights from successful approaches that have delivered tangible results, the following preconditions for an effective EU regulatory burden reduction program can be identified:

#### **Focus on low-burden policy instruments**

The SCM has played a crucial role in quantifying regulatory burden by identifying the key parameters that determine the regulatory costs to comply with the legislation. This model has clarified how factors such as time investment, frequency of obligations, and external costs contribute to the administrative burden on businesses.

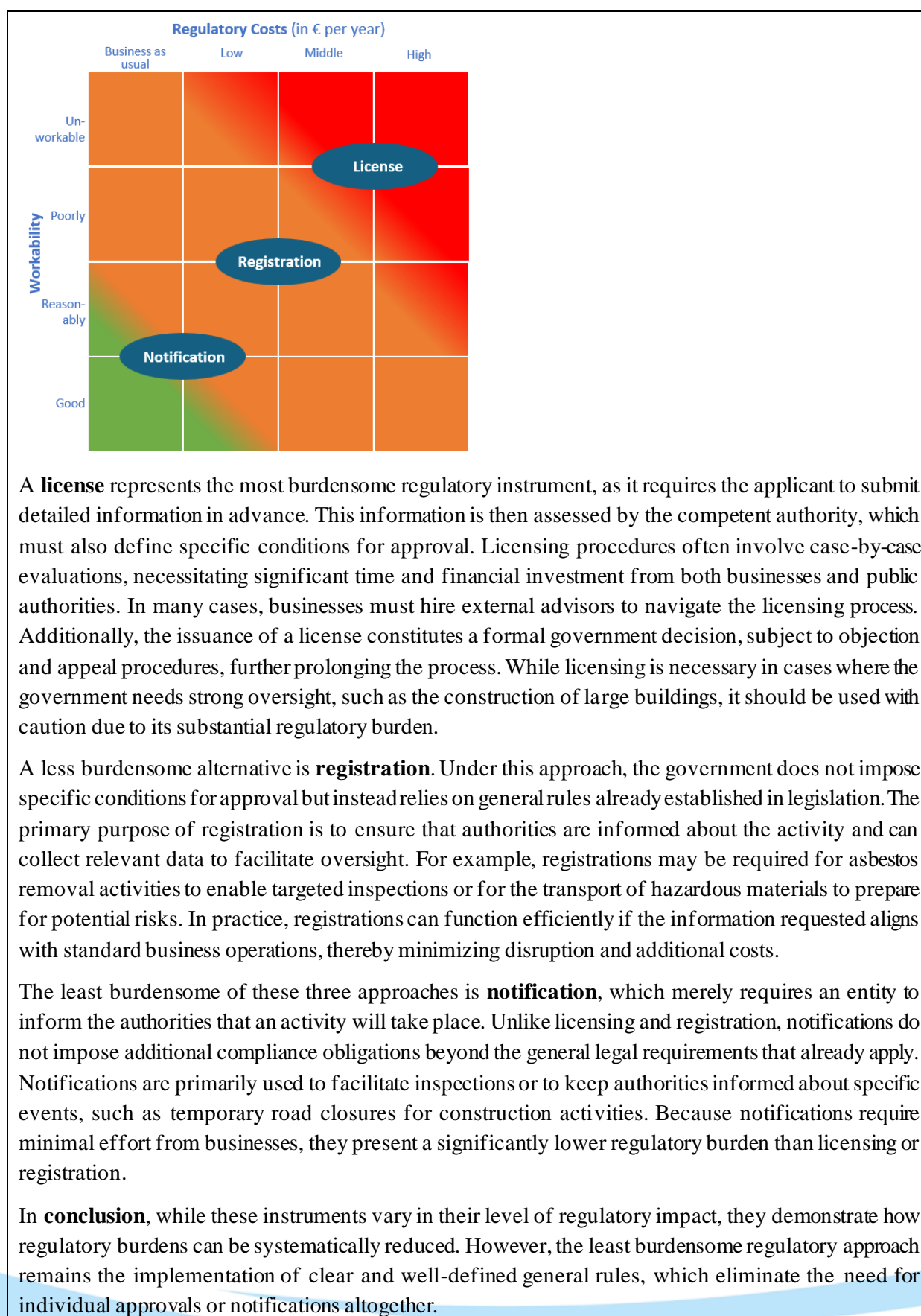
Building on this foundation, the SME indicator company approach has further refined these insights by examining not only the objective costs of compliance (regulatory costs) but also the workability of regulatory obligations within business operations. This research has demonstrated that the same regulatory requirement can be perceived very differently across businesses, depending on how well it aligns with existing processes. As a result, beyond direct regulatory costs, factors such as clarity, feasibility, and reliance on external expertise play a decisive role in determining the perceived regulatory burden.

Based on these insights, heuristics (practical rules or guiding principles derived from experience) have been developed to predict in advance whether a specific obligation is likely to create a high regulatory burden. These heuristics provide policymakers with a structured way to assess the potential complexity, administrative impact, and feasibility of compliance requirements before they are introduced. This understanding of 'low-burden policy instruments' enables policymakers to proactively design legislation that minimizes regulatory burden while maintaining regulatory objectives, ensuring that regulations remain effective without imposing unnecessary burdens on businesses.

To illustrate the concept of low-burden policy instruments, the textbox below illustrates three regulatory approaches that progressively reduce regulatory burden and administrative complexity: licensing, registration, and notification.



## Textbox 2. Example low-burden policy instruments



### **New regulation: Robust control and consistency over the whole process of law-making (including implementation in Member States).**

For new legislation to be effective, it is essential that its implementation is fully developed at the level of the entrepreneur before it comes into force. This is particularly crucial for SMEs, which lack the legal and administrative capacity of larger corporations. Unclear regulations create uncertainty and excessive regulatory burden, forcing smaller businesses to seek costly external support. A clear example is the introduction of EU privacy regulation, where many companies struggled with interpretation and implementation, leading to additional expenses for external advisors and consultants.

To prevent such issues, greater investment in the early development phase of legislation is necessary. This requires stronger engagement from public authorities and regulatory bodies (both at the EU level and within Member States) to ensure that regulatory requirements are fully operationalised before they take effect. By considering practical feasibility early in the process, unnecessary administrative burdens can be avoided, and regulations can be introduced in a clear, predictable, and implementable manner for businesses.

In addition, a more robust approach is needed to discourage ‘gold-plating’, the practice of Member States adding extra national obligations on top of EU legislation. Without stronger coordination, businesses will continue to face unequal compliance costs and inconsistencies in implementation, undermining the level playing field within the Single Market.

To a certain extent, the European Commission already addresses this issue through the choice in individual cases between one of the two legislative instruments the Treaty provides: EU Directives and EU Regulations. Directives require transposition into national law, often leading to variation in implementation across Member States, whereas Regulations are directly applicable, ensuring greater legal consistency. Recognising this, the Draghi Report has recommended increasing the use of EU Regulations to enhance harmonisation and reduce regulatory fragmentation across the EU.

However, despite their direct applicability, Regulations can still be subject to differing interpretations by Member States, which may undermine their intended harmonising effect. This is evident in the case of Article 19 of EU Regulation 178/2002 (General Food Law), case 2, where discrepancies in national enforcement approaches have led to inconsistencies in how businesses must respond to food safety risks. Such variations highlight the need for mechanisms that ensure a uniform application of Regulations across the EU. While expanding the use of Regulations can improve legal alignment, additional efforts are required to address divergences in interpretation and enforcement to fully achieve regulatory consistency.

#### **Case 5. General Food Law, interpretation of an EU Regulation**

The Netherlands has a high level of food safety. The food industry consists of many processing companies operating within a market radius of 800 km around the country. These companies benefit from effective supervision and a resulting high level of food safety.

Article 19 of EU Regulation 178/2002, ‘General Food Law’<sup>1</sup>, stipulates that a food product that has been placed on the market and may be harmful to health must be reported “without delay” and “immediately” to the authorities by the companies involved.

## **Impact**

Article 19 obliges companies to immediately withdraw unsafe food from the market, warn consumers, and cooperate with authorities to manage health risks.

- In 2022, the Dutch Ministry of Health, Welfare, and Sport (VWS) tightened the interpretation of EU Regulation 178/2002 by introducing an official policy rule (no. 16878)<sup>2</sup>, which sets a strict four-hour timeframe. Within these four hours, companies must notify the NVWA (Netherlands Food and Consumer Product Safety Authority) of these procedures and the measures taken.
- In addition, in 2024, the NVWA further expanded the reporting obligation beyond just harmful products, now also requiring companies to report "suspicions of a deviation".

Regulatory authorities in other EU Member States do not impose such strict reporting obligations or apply longer reporting deadlines, following an interpretation more in line with European legislation.

## **Different implementation**

Since the tightening of regulations by VWS (2022) and NVWA (2024), administrative burdens have increased drastically. The Federation of the Dutch Food Industry (FNLI) observed the following:

- A company that previously had to file around 7 reports per year must now submit 97 reports, navigating the digital NVWA reporting system.
- Instead of investigating the root cause of a potential issue, companies are now primarily focused on meeting the four-hour reporting deadline.
- Previously, only harmful products had to be reported (unless there was a recall), but now even minor (possible) deviations must be reported. Examples: a batch of raisins containing a small twig, or a consumer complaint about glass, which later turns out to be an ice crystal.

For comparison, in Belgium, companies have 48 hours to report an issue. The reporting obligation applies only to harmful products, not to suspected deviations (except in case of a recall). Before submitting a report, there is room for a risk assessment by the company itself.

The Dutch situation consumes significant time and resources for both companies and the NVWA, without adding value to public health. The time spent on unnecessary reporting could be better utilised to address real risk (e.g., blocking stock, providing information across the supply chain). However, due to the current policy, companies are now forced to choose between reporting or taking action, making the broad interpretation of the law counterproductive to food safety.

## **Improvements**

The FNLI is organising a legal discussion and a roundtable meeting to explore solutions together with the Dutch Ministry of VWS and the NVWA.

1. <https://eur-lex.europa.eu/eli/reg/2002/178/oj/eng> EU Regulation 178/2002, 'General Food Law'.

2. <https://zoek.officielebekendmakingen.nl/stcrt-2022-16878.html> Dutch Ministry of Health, Welfare, and Sports (VWS). Policy rule no. 16878.

### **Existing regulations: clear, quantitative reduction targets based on measurable data and a transparent methodology for a baseline measurement and monitoring the reduction target**

For regulatory burden reduction to be effective within existing legislation, it is essential to gain a clear understanding of how (SME) businesses actually implement compliance obligations across the EU. By analysing regulatory burden (regulatory costs and workability) from a practical perspective, it becomes evident where regulations create bottlenecks in real-world business operations and which obligations are perceived as the most burdensome by entrepreneurs. This approach also provides valuable insights into variations between Member States, highlighting inconsistencies in implementation.

A critical step in this process is linking this analysis to the principle of a baseline measurement. By first measuring the practical impact of regulations, quantifiable targets can be formulated that directly reflect the realities businesses face. This ensures that reduction measures are not only effective on paper but also tangibly reduce burdens for businesses in practice.

The SME indicator company approach serves as a valuable instrument in this effort. By mapping regulatory burden at an indicator company, concrete insights can be obtained into both the actual regulatory costs and the workability of obligations. The underlying assumption is that reducing regulatory burden at an indicator company will have a broader positive impact on other SMEs within the same sector. This makes it possible to implement targeted, realistic measures that structurally reduce administrative burdens without undermining policy objectives.

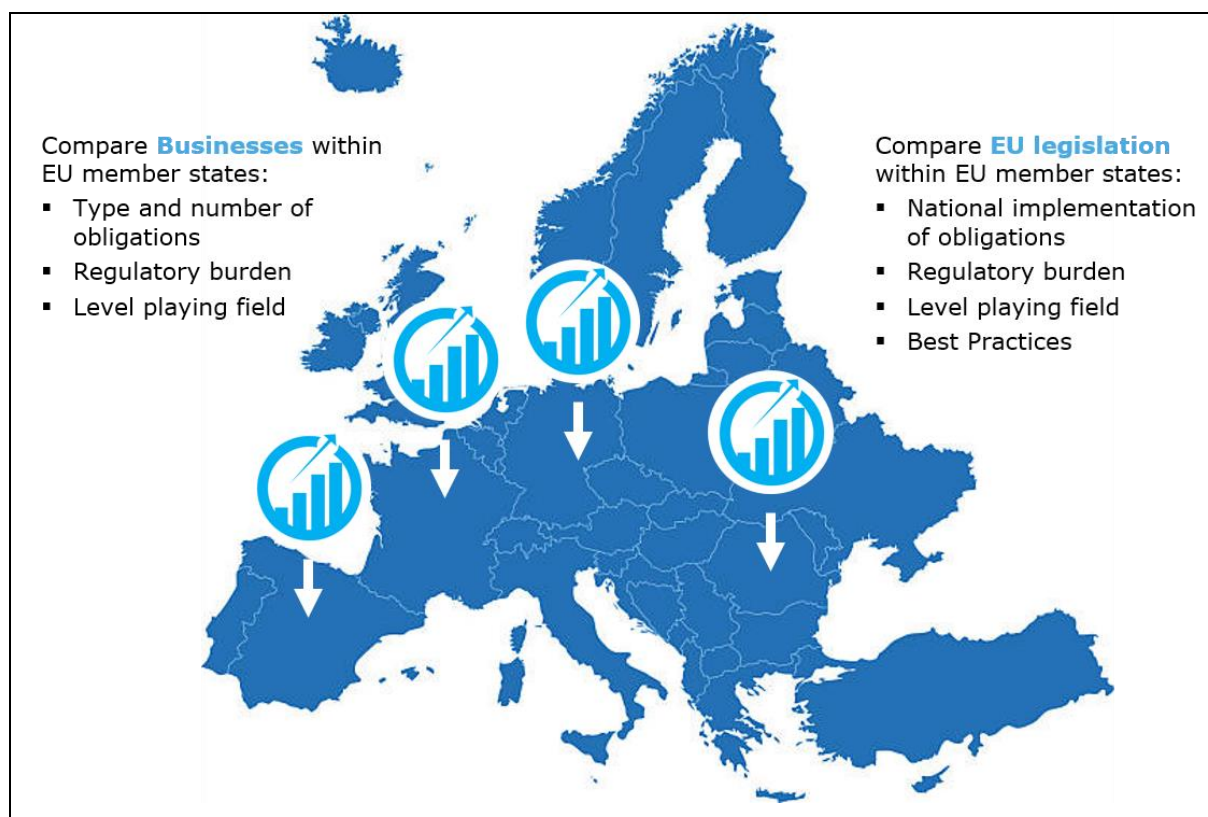
#### **Textbox 1. The concept of SME Indicator companies across the EU**



The indicator companies approach is inspired by the concept of indicator species in biology. In ecological monitoring, the health of an ecosystem is assessed by examining the condition of specific species that serve as indicators. The underlying principle is that if these species thrive, the overall ecosystem is likely in good condition as well.

Applying this logic to the economy, we identify specific businesses as indicator companies to systematically monitor regulatory burden and competitiveness. By focusing on these representative businesses, we gain a clear, quantifiable, and reliable understanding of how regulations impact economic activity. This approach makes the effects of regulatory pressure more tangible and facilitates targeted policy improvements.

By measuring the cumulative costs of regulation for these indicator companies, we can compare regulatory burdens across Member States and identify differences in the implementation of EU regulation. This allows for a more precise assessment of how variations in national transposition and enforcement affect businesses, making it easier to pinpoint inefficiencies and promote greater regulatory harmonisation across the EU.



**An enforcement mechanism to ensure objectives are met and regulatory burdens are effectively reduced.**

Regulatory burden reduction programs are most effective when they are guided by clearly defined objectives and supported by enforcement mechanisms that ensure tangible results. Without such structures, commitments to reduce regulatory burdens risk becoming aspirational rather than actionable. Best practices from Member States demonstrate that institutional anchoring and systematic progress monitoring are key success factors.

In the Netherlands, from 2002 to 2010<sup>28</sup>, the regulatory burden reduction program was fully or partially placed under the Ministry of Finance. Progress on reduction targets was systematically reviewed as part of the annual budget discussions of individual ministries. This direct linkage to financial oversight created strong incentives for compliance and contributed to the achievement of ambitious reduction goals. Major steps were taken during this period, including the replacement of permit requirements with general rules, often supplemented by notification or registration obligations.

Similar mechanisms in other Member States, such as the UK and Germany, have proven instrumental in achieving regulatory simplification targets. By embedding burden reduction within broader governance and budgetary frameworks, these approaches ensure that commitments translate into measurable outcomes, fostering a more predictable and efficient regulatory environment across the EU.

28 MKB Nederland – Sira Consulting - Analysis of Regulatory Burden Reduction Programs of the Dutch Government (1998 - 2020) Den Haag, Maart 2021



### 3.4 The Regulatory Burden Index

Assessing regulatory burdens within the EU remains fragmented. While the European Commission employs the Standard Cost Model to quantify regulatory costs, its application is inconsistent across legislation. The European Parliament and Council lack a standardized approach to evaluating the impact of amendments, and Member States have significant discretion in implementation, leading to inconsistencies that complicate measurement and oversight.

Current (impact assessment) methods are time-consuming, relying heavily on business consultations and consultancy and research institutes to estimate regulatory costs to comply. Few Member States systematically assess the impact of transposed EU law, further limiting transparency and comparability. This lack of standardization hampers effective scrutiny and makes it challenging to develop targeted regulatory burden reduction strategies.

A possible approach to develop a more uniform way of dealing with regulatory burden is the Regulatory Burden Index. The Regulatory Burden Index serves as both an (AI driven) analytical and a preventive tool, designed to provide clear insights into the regulatory burden imposed by proposed or existing legislation. On one hand, it quantifies the extent to which regulations create administrative burdens, offering a structured assessment of the regulatory costs and the workability. On the other hand, it is primarily intended as an instrument to prevent or reduce regulatory burdens by making explicit the heuristics associated with certain obligations (such as the principle of low-burden policy instruments) and the metrics that determine the scale of regulatory costs. These metrics include quantitative parameters such as time investment, external costs, frequency of obligations, and the number of affected businesses.

By systematically mapping the regulatory burden, the index enables policymakers to evaluate the impact of legislative proposals before they are introduced, ensuring that potential regulatory costs and administrative complexities (workability) are fully understood. More importantly, it provides concrete guidance on how to streamline obligations and mitigate unnecessary burdens. The goal is not merely to quantify regulatory costs but to use this quantification as a means to gain deeper insight into the burden imposed by regulations and to make the effects of simplifications explicitly visible.

Ultimately, the Regulatory Burden Index serves as a dual-purpose tool: it rates the burden caused by a regulation or directive while simultaneously offering actionable recommendations to minimize regulatory pressures. This approach ensures that regulatory simplification efforts are both data-driven and effectively targeted, enhancing the overall efficiency of the regulatory framework.

The ultimate outcome of the Regulatory Burden Index is a comprehensive overview of what regulations concretely mean for businesses. This includes a clear listing of all obligations, the (SME) businesses they apply to, and the exact steps required for compliance. Additionally, the index provides insight into the government bodies responsible for enforcement, distinguishing between the authority overseeing implementation (such as registration requirements) and the authority responsible for supervision, specifying what information must be available for oversight. This structured approach aligns with

ongoing initiatives, such as those in the Czech Republic<sup>29</sup>, aimed at increasing transparency and predictability for businesses.

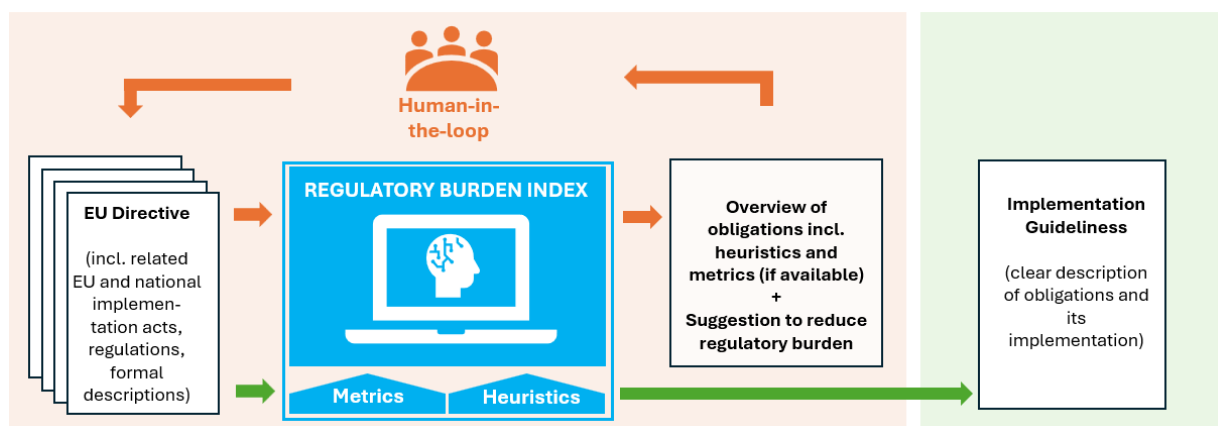


Figure 6 Impression of Regulatory Burden Index

### 3.5 Concluding remarks

Despite significant efforts to enhance the Better Regulation agenda, businesses, particularly SMEs, continue to face a growing regulatory burden that hinders competitiveness, innovation, and economic growth. A key structural challenge is that EU regulation evolves unpredictably throughout the legislative process, creating uncertainty and unforeseen compliance costs. Frequent amendments and varying national implementations turn regulation into a moving target, making it difficult for businesses to plan and adapt efficiently.

While individual regulatory tools such as Impact Assessments, SME Tests, and the OIOO principle aim to mitigate unnecessary burdens, their effectiveness remains limited. To move from intention to impact, regulatory burden reduction must be approached systematically, transparently, and with the entrepreneur's perspective at its core. Establishing a common EU-wide methodology, potentially supported by AI-driven analysis tools, could provide consistent, real-time insights into the cumulative effects of regulation. AI has the potential to identify redundancies, assess workability, and quantify regulatory costs more efficiently, enabling policymakers to make data-driven decisions that result in real, measurable relief for businesses.

A regulatory environment that is clear, predictable, and efficiently managed is essential for fostering a stronger, more competitive European economy. Without decisive action to harmonise implementation, improve measurement frameworks, and leverage technological advancements, regulatory burden will

<sup>29</sup> There are already several examples of good practice in the Member States on how to better regulate and evaluate the impact of legislation throughout the political cycle. One of them is the example of the Czech Republic, where the legislators are obliged by the law to accompany every legislative act with a summary of legal obligations arising from it. Informative overview of public law obligations arising from the draft legal regulation (an informative table) is in the annex to Act n° 222/2016 Coll. Although this law has not yet entered into force, the Czech Chamber of Commerce, who stands behind the idea of such informative tables, has already mapped the obligations for entrepreneurs in the Czech legislation six years ago, and developed on its basis a digital "Legal Electronic System for Entrepreneurs". It is a unique tool developed with large number of lawyers who analysed the national legislation in details. This allowed the creation of a database for entrepreneurs showing them on a daily basis their legal obligations and the way how to deal with them, while filtering a set of obligations according to the size and sector of each entrepreneur. Such a system could be easily replicated in another country and at EU level, under the condition that legislators and regulators are willing to create consistency and efficiency in their regulatory work.

continue to grow, limiting the entrepreneurial potential and economic resilience of the EU. A Business-Centric Approach to Cutting Red Tape requires not just better regulation, but efficient regulation. One that prioritises practicality, transparency, and business-friendly execution at every stage of the policymaking process.



## 4. The AI-supported Regulatory Burden Index

### 4.1 Functional overview

The Red Tape AI tool is developed with the goal of automating analysis of regulatory burden stemming from EU legislation. The objective is to create an instrument that enables tight feedback cycles when developing new EU legislation (ex-ante) as well as analyses and comparisons of regulatory burden in existing legislation (ex-post). To achieve this while retaining a governable process, the AI tool works by mimicking (at least in part) the steps of a manual assessment of regulatory burden in legislative texts and is to this end equipped with corresponding expert domain knowledge that is modelled in a machine-digestible format.

The system can then be implemented by automating these assessment steps using modern AI technology (such as semantic text embeddings and leveraging large language models) as well as more traditional software development methods, which will be explained in more detail below. While the modular nature of the tool makes it suited to analyse different types of regulatory burden, the focus of development described below is on the extraction and evaluation of information obligations. Note that it is possible to extend the tool's scope to include other dimensions of regulatory burden such as, for instance, analyses of compliance obligations regarding competitive positioning. Just as with the current scope, such an extension necessitates extensive knowledge modelling for the corresponding areas of extension.

The design of the AI tool is rooted in four core principles:

1. Explicit knowledge modelling as a factual base to safeguard accuracy: instead of relying on implicitly learned knowledge that is present in many modern AI systems (e.g. large language models such as ChatGPT), the analysis methodology and parameters are explicitly modelled as the backbone of the tool. This prevents inaccuracies in the output by making sure that the automated analysis follows a controlled process.
2. Supervised AI methods to assure output relevance: the analysis methodology of the legal texts is built on machine learning methods that select only the relevant parts for further processing. This reduces noise in the data that is used to evaluate regulatory burden and prevents consideration of irrelevant data.
3. Leveraging large language models (LLMs) to extract information from large amounts of text in multiple languages: while current AI systems such as ChatGPT are still somewhat lacking in reasoning-related tasks and tend to hallucinate (i.e. produce non-factual information), they have good information extraction and summarization capabilities, in a multitude of languages. The tool relies on these to identify and compile regulatory burden-related information from legal texts.
4. Human-in-the-loop to continually improve performance: the tool is designed in a modular fashion that allows for easy amendment of its training data in an evaluation context, to improve its output analyses. Furthermore, it can be extended with a conversational interface that enables a more direct approach for a human to interact with analysis results.

Note that the role of LLMs in this design is deliberately limited to information extraction tasks. To be effective, it is vital that an AI tool “sticks to the facts” and does not try to draw conclusions from a textual context in which an LLM perceives them to be possible or likely. Thus, a more structured approach is necessary where the LLM is guided and kept in check by guardrails that are provided through

harnessing the expertise and experience gathered in earlier (non-AI assisted) initiatives to reduce regulatory burdens, and a more controlled usage of supervised AI methods. In this way, a general-purpose LLM is augmented with domain-specific capabilities that allow for the creation of a precision instrument suited to carry out the specific tasks required for evaluating regulatory burden. The figure below shows the functional schematics of the AI tool.

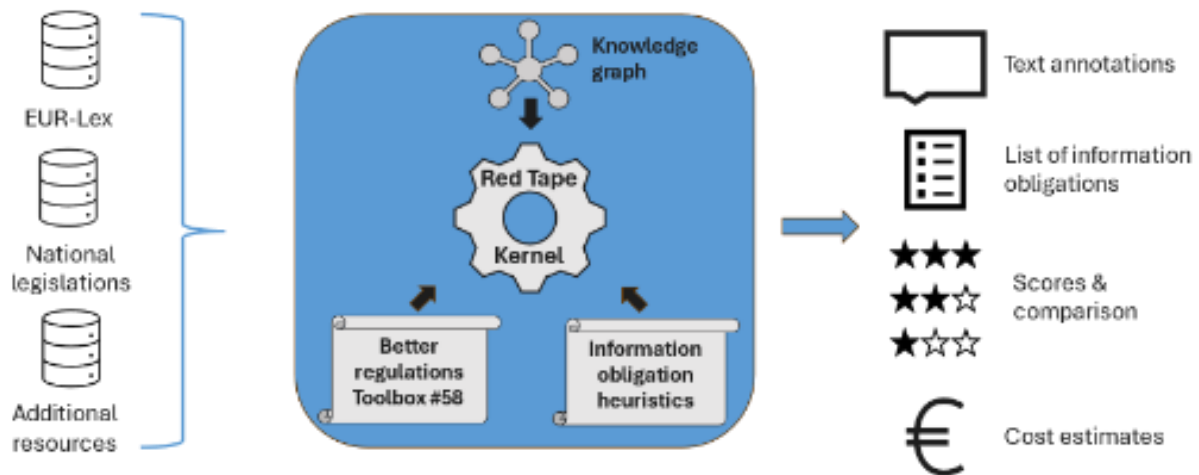


Figure 7 Functional schematics

From a functional perspective the tool is designed as follows: legal texts published on EUR-Lex (e.g. regulations, directives, delegated acts) together with their national implementations and supplemental materials are passed in textual form to the AI tool. The tool then performs an automatic analysis of these inputs, and creates different outputs suited to assess the possible obligations in the input texts:

- Text annotations: passages in the input texts that are possible sources of information obligations are highlighted as such and annotated with the corresponding type(s) of obligation.
- List of information obligations in the input texts: a summary of all information obligations present in the input is created, detailing the types of obligations, a short description and further related information such as obligation frequency or the types of affected businesses.
- Scores and comparisons: input texts can be scored on different dimensions of information obligations (e.g. by number of obligations per type, severity, etc.) and/or with an aggregate score to enable comparisons between different pieces of legislation (e.g. across different national implementations or across different regulations).
- Cost estimates: using the extracted information and formulas such as those provided in Better Regulations Toolbox #58 expected costs stemming from input legislation can be estimated.

## 4.2 Component descriptions

Zooming in on the inner workings of the AI tool, this section describes in further detail how the analysis engine is implemented.

### Training data

To ensure the correct focus of the AI analysis, a detailed set of training data for the tool is assembled. This encompasses knowledge modelling based on the EU Standard Cost Model (Better Regulations Toolbox #58) as well as heuristics collection from regulatory burden experts and modelling supplemental data in a knowledge graph:

- The EU SCM comes with a detailed description of possible regulatory burdens and a definition of administrative costs for businesses. The relevant parts of Toolbox #58 have been extracted and collected.
- Regulatory burden experts created heuristics concerning the different dimensions of information obligations for businesses that can stem from EU legislation, specifically for the AI tool. Fourteen dimensions of information obligations have been identified. They have been rated according to the perceived severity of regulatory burden they typically introduce on businesses and enriched with definitions and examples from legislative texts illustrating them. While those definitions and examples play a crucial role in identifying information obligations in legislation texts, the severity ratings enable the AI tool to put them on a scale suited for overall comparison of introduced regulatory burden.
- Depending on output needs, additional training data can be provided to the AI tool in the form of a knowledge graph. This could e.g. entail specifics on national administration structures when assessing national implementations or industry statistics for calculating a cost estimate.

The AI tool is trained on and guided by the information below as described in the following section. Note that the design of the tool is flexible concerning its training data: it is not essential to the system that the exact same heuristics as worked out for this project are used as input. For instance, by expanding the information obligation heuristics with different types of obligations, the scope of the tool can be expanded. Similarly, the design of the tool allows for amendment of the current set of training data after expert evaluation: in this way the human-in-the-loop principle is ensured, and the performance of the AI tool can be continually improved by letting experts review its output. For instance, new examples of regulatory burden from existing legislation can be added to a heuristics dimension to improve detection accuracy or the severity ratings of the different dimensions can be adjusted to improve comparability of analysis results.

High Regulatory burden	License	License processes often generate high regulatory burden. They are time-consuming, require detailed applications, compliance with complex regulations, and possibly external reviews. Multiple approvals may be necessary.
	Permit	Permits are similar to Licenses but often relate to ongoing activities. They may involve recurring requirements, periodic renewals, and audits, adding time and costs.
	Certification	Certifications often require extensive audits and compliance processes to meet specific standards. The involvement of external certifying bodies increases both costs and burden.
	Reporting	Reporting obligations are typically complex and time-intensive, especially when frequent and detailed data submissions are required. The administrative load and risk of errors can be significant.
	Audits	Audits generate high administrative pressure due to preparation, documentation, and involvement of external parties. They are often expensive and time-consuming.
	Inspections	Inspections create immediate pressure due to compliance demands, the risk of penalties, and potential disruptions to operations.
	Monitoring	Monitoring involves ongoing processes, such as data collection and analysis, which can generate long-term regulatory burden, whether imposed internally or externally.
	Application	Application procedures are usually one-off but can be complex depending on the information required and approval processes involved.
	Registration	Registration obligations are typically less burdensome as they are often one-time administrative requirements. However, they still require time and compliance.
	Notification	Notification requirements are relatively straightforward and impose limited administrative burden. They are often informational and do not require formal approvals.
Lower Regulatory burden	Investigation	Investigations can be intensive but are usually situational and less frequent, resulting in lower structural regulatory burden.
	Plans	Developing plans is primarily an administrative task. While the level of detail may vary, it is generally less burdensome than reporting or audits.
	Labelling	Labelling requirements are specific and practical, focused on transparency and information-sharing, causing relatively low structural burden.
	Informing	Informational obligations are typically the least burdensome. They involve sharing data without significant administrative or technical requirements.

Figure 8 Example of heuristics

## The Red Tape Kernel

The Red Tape Kernel is the core functionality of the AI tool. The essence of its inner workings lies in how the training data described in the previous section is used to reliably perform the analysis tasks mentioned in the functional overview. As explained below, the domain-specific knowledge and logic encoded in the training data plays an essential role in all the processing steps of the system. This approach is needed to turn general-purpose generative AI models (in this case LLMs) into specialised tools that can accurately carry out the task at hand. Specifically, it allows us to restrict the usage of the LLM to its extractive and semantic understanding capabilities but avoid relying on interpretation and LLM-internal knowledge which are infamous for introducing inconsistencies and hallucinations in its output.

### Step 1. Annotating information obligations via semantic search

As a first step in the processing pipeline, the AI tool marks text passages from input legal texts when they are likely to contain an information obligation for businesses. This works by producing *semantic embeddings* of the definitions and examples that belong to the different heuristics dimensions for information obligations.

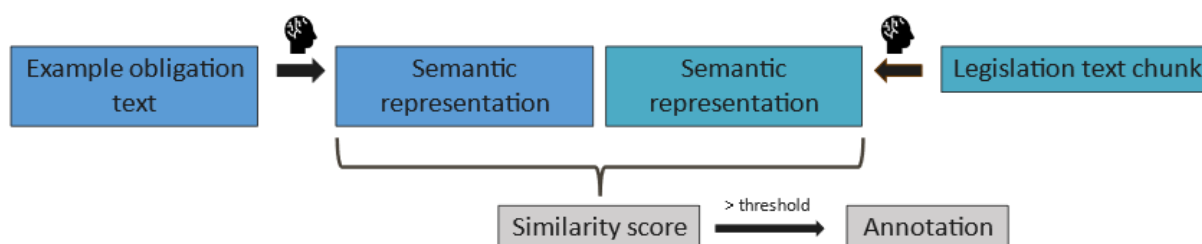


Figure 9 Text passage annotation logic

It is achieved by transforming these textual pieces of information into vectors of numbers, usually with the help of an external sentence embedding model (e.g. *text-embedding-3-large* by OpenAI). These numerical representations encode the *meaning* of the encoded text passage rather than their syntactics: when two pieces of text are encoded by such a model, the respective output vectors will be close (by a suitable numerical measure) if the meaning of the two pieces of text is similar.

To identify possible sources of information obligations in the input texts, they are split into smaller passages, which are in turn encoded by the sentence embedding model and compared to all embeddings of the definitions and examples from the obligation heuristics. Whenever their similarity measure is above a certain threshold, the input text passage is annotated as containing the corresponding type of obligation, with a confidence score depending on the magnitude of the similarity measure.

While the annotations produced in this processing step form an important input for further analysis by the tool, they can also give the user insights on how the tool extracts information obligations from the given source texts and as such serve as evaluation input, implementing the human-in-the-loop principle.

## Step 2. Extracting information obligation summaries

To extract an overview of all information obligations from an input text, an external LLM (e.g. GPT-4 by OpenAI) is first instructed with definitions of Toolbox #58, information obligation heuristics definitions and relevant parts of the knowledge graph. It is crucial to provide this information to the LLM to ensure that it can carry out its tasks as intended and without hallucinations. Then, the LLM is then tasked to extract information obligations and their details (e.g., frequency, affected types of businesses) from the *annotated* input texts of the previous step and put them into a structured, tabular form. Again, the text annotations are crucial in this step to guide the LLM's focus to the relevant passages in the input texts.

In a final step, it is possible to use the knowledge graph to check the extraction results. For example, it may be known a-priori that, in a given context, certain types of obligations cannot occur. In this case, misclassifications can be corrected either immediately by applying a rule (in simpler cases) or by resubmitting the task to the LLM in amended form (for more complex situations).

*"You are an expert analyst specialising in evaluating administrative costs as defined by the EU Standard Cost Model (Better Regulations Tool 58): .... Assess administrative costs stemming from information obligations for businesses which are laid out in the following matrix: .... Scan the source legislative text from beginning to end and produce a table that exhaustively lists all the information obligations for businesses in the legislative text as explained above..."*

Figure 10 Example LLM prompt for obligation extraction

## Step 3. Regulatory burden scores and comparisons

To evaluate legislation regarding regulatory burden stemming from information obligations numerically, the output of the previous analysis step can be used. For example, for each dimension of regulatory burden specified in the training data heuristics, the number of information obligations can be counted. Furthermore, using the results of the previous step, the tool can identify obligations where important implementation characteristics are not explicitly present in a legislative source text and hence may lead to an increased risk of regulatory burden when they are specified further in the legislative process (see cases 1, 2 and 3). These obligations may be flagged as carrying an elevated risk, and e.g., counted with extra severity. These approaches already allow for comparisons between different legislative texts concerning their sources of regulatory burdens.



To compare multiple pieces of legislation on the overall severity of regulatory burden they may impose, a weighted sum over scores in the individual heuristics dimensions can be calculated, where, for example, an obligation to obtain a permit is weighed more heavily than an obligation to periodically notify an authority (see figure 9). In this way a regulatory burden index is created that makes it possible to rank legislation based on the expected impact of their expected imposed regulatory burdens. Note that depending on the weights, this index may not only measure costs but also encapsulate other aspects of regulatory pressure from legislation, such as impact on daily operations. Thus, having a clear measurement target for the overall regulatory burden severity is important when defining the heuristics weights, as different numerical choices may reflect different aspects of regulatory burden.

In a further step, overlapping information obligations in a set of legislative texts may be detected by letting the LLM evaluate the summaries of obligations for each text jointly. This builds upon the LLM's ability to produce detailed summaries of the individual obligations in the previously described step. Implementing this functionality also entails providing the LLM with detailed instructions and guardrails to assure high-quality results and avoid hallucinations.

#### Step 4. Cost estimate calculations

In a parallel post-processing step, the obligation summaries produced by the LLM can be used to produce estimates of administrative costs for the businesses affected by the legislation. To do this, it is necessary to:

1. Provide the AI tool with a formula to calculate a cost estimate for a given obligation, e.g. as the "Core Equation" provided in the EU SCM (Better Regulations Toolbox #58). The formula can be encoded in the knowledge graph as part of the tool's training data.
2. Extract the input parameters of the formula from the input legislative texts. The parameters should be specified in the LLM's prompt for the obligation summary extract. However, the provided legal texts may not specify all the required input parameters. For example, to calculate the total administrative costs for an information obligation, it is necessary to know the total number of affected businesses, which is rarely stated explicitly in the legislative text from which it originates. In these cases, one may ask the tool's user to provide the missing data (see also section 4.4), require more textual input from which the information can be extracted or opt to "fill in the blanks" automatically by specifying generic estimates for missing parameters in the knowledge graph training data. In the latter case, produced estimates will lose accuracy and should be marked as such.

Once these conditions have been fulfilled, the tool will be able to evaluate the formula for each detected obligation and sum the individual results to calculate the total estimated administrative costs of the input legislation.

This processing step of the tool can also be integrated into a workbench-like environment for new legislation. Based on heuristics such as in figure 9 **Error! Reference source not found.** the system can alert the user to possible sources of regulatory burden in drafts of legal texts: where the legislation details allow, cost estimates can be calculated, but it can also flag information obligations in the texts where not enough information is present to provide a cost estimate and hence a high *risk* of introducing regulatory burden is present. In the latter cases, the tool may give an indication in which quadrant of the matrix in figure 4. the risk lies. The user may then choose to revise the affected parts of the legislation, possibly incorporating improvements that are also suggested by the system.

$$Cost = \sum P \times Q$$

Figure 11 Simplified formula for administrative costs from the EU SCM

Note that this functionality of the AI tool provides a uniform way to measure and compare administrative costs of national implementations of EU legislation in the Member States: letting the tool analyse the legislative texts of the national implementations, their associated administrative costs are calculated by the same methodology and formula which makes the results comparable.

### 4.3 Output examples

In this section we present some example outputs of the AI tool when it is fed EU legislative texts from EUR-Lex.

#### Text annotations

Below is an article of Regulation 2024/1760 on Corporate Sustainability Due Diligence which the tool has annotated as containing a reporting obligation.

**Reporting**

- **Similarity score:** 0.60 **Chunk index:** 183

Article 16 Communicating 1. Without prejudice to the exemption provided for in paragraph 2 of this Article, Member States shall ensure that companies report on the matters covered by this Directive by publishing on their website an annual statement. That annual statement shall be published: (a) in at least one of the official languages of the Union used in the Member State of the supervisory authority designated pursuant to Article 24 and, where different, in a language that is customary in the sphere of international business; (b) within a reasonable period of time, but no later than 12 months after the balance sheet date of the financial year for which the statement is drawn up, or, for companies voluntarily reporting in accordance with Directive 2013/34/EU, by the date of publication of the annual financial statements. In the case of a company formed in accordance with the law of a third country, the statement shall also include the information required pursuant to Article 23(2) regarding the company's authorised representative. 2. Paragraph 1 of this Article shall not apply to companies that are subject to sustainability reporting requirements in accordance with Article 19a, 29a or 40a of Directive 2013/34/EU, including those that are exempted in accordance with Article 19a(9) or Article 29a(8) of that Directive.

Figure 12 Example of a text annotation

The obligation is mentioned in the first paragraph of Article 16, where businesses are required to publish an annual statement on their website. The AI tool also provides a similarity score, which measures the semantic similarity of the given passage to the relevant parts of its training data examples and ranges from -1 (very dissimilar) to 1 (almost identical). The “chunk index” as seen in the figure above is only of technical nature and indicates the position of the text passage in the input document (the regulation text in this case).

#### Obligation summary tables

Below, a part of an obligation summary table is shown which has been produced by the AI tool after analysing Regulation 2024/1760 on Corporate Sustainability Due Diligence.

Obligation Type	Obligation Frequency	Obligation Description	Text Reference
Notification	N/A	Establishment of a notification mechanism for parties to submit information or concerns regarding adverse impacts.	Article 14, paragraph 5
Registration	Once	Designation of an authorized representative by third-country companies operating in the Union.	Article 23, paragraph 1
Reporting	Yearly	Requirement for companies to publish an annual statement on their website detailing due diligence measures.	Article 16, paragraph 1
Informing	N/A	Obligation to provide relevant and comprehensive information during stakeholder engagement processes to ensure effective consultations.	Article 13, paragraph 2

Figure 13 Example obligation summary table

Note that the reporting obligation annotation of the previous step also appears in this table, this time with a short description, a frequency and a reference to the relevant part of the regulation text. For some obligations a frequency could not be determined from the source text and have hence been marked with “N/A”. In this case, the obligations marked as such are situation-specific and hence do not necessarily have a fixed frequency.

In general, the tool can also be tasked with extracting other obligation details that are relevant for further interpretation and/or processing. It is, however, clearly tasked with an extraction, meaning that no attempt should be made to infer obligation details that are not explicitly mentioned in the input legislation.

### Scoring and comparing legislative texts

During the development of the tool, a set of more than 1.800 regulations and directives has been collected from EUR-Lex, including all those that came in to force 2019-2024. For each of those, the AI tool identified information obligations and scored regulatory burden according to the heuristics dimensions in Figure 7. Below, a subset of 10 regulations and directives from EUR-Lex are compared regarding the number of information obligations for business that have been detected by the AI tool.

The format below makes it possible to compare the different pieces of legislation on different information obligation heuristics dimensions. Furthermore, considering the total sum of detected information obligations or a weighted variant thereof (the “RB index”) leads to a comparison between the total regulatory burden the considered regulations and directives introduce. In this case, a simple linear scale has been used for the heuristics weights, for illustration purposes. Using the ordering in Figure 7, “License” is assigned the highest of the weights, which then decrease linearly across the different heuristics dimensions until “Informing”, which is assigned the lowest weight.



	Title	Permit	Registration	Notification	Reporting	Monitoring	Inspections	Certification	Audits	Plans	Informing	Labelling	License	Application	Investigation	Total	RB index
32024R057	Regulation (EU) 2024/573 of the European Parliament and of the Council of 7 February 2024 on fluorinated greenhouse gases, amending Directive (EU) 2019/1937 and repealing Regulation (EU) No 517/2014 (Text with EEA relevance)	0	2	0	5	3	0	4	1	0	0	0	0	0	0	15	10.64
32018R113	Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (Text with EEA relevance.)	0	0	2	1	0	0	8	2	1	0	0	0	0	0	14	10.00
32022L246	Directive (EU) 2022/2464 of the European Parliament and of the Council of 14 December 2022 amending Regulation (EU) No 537/2014, Directive 2004/109/EC, Directive 2006/43/EC and Directive 2013/34/EU, as regards corporate sustainability reporting (Text with EEA relevance)	0	0	0	4	1	0	3	5	0	1	0	0	0	0	14	9.93
32021R211	Regulation (EU) 2021/2116 of the European Parliament and of the Council of 2 December 2021 on the financing, management and monitoring of the common agricultural policy and repealing Regulation (EU) No 1306/2013	0	2	0	4	2	2	1	3	1	0	0	0	0	0	15	9.64
32014L003	Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (recast) Text with EEA relevance	0	2	2	3	1	0	5	1	0	0	1	0	0	0	15	9.64
32018R084	Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007	0	0	5	4	0	1	3	1	0	0	1	0	0	0	15	9.00
32023R154	Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC (Text with EEA relevance)	0	1	2	4	1	0	3	1	0	2	0	0	0	0	14	8.29
32017R074	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance.)	0	2	1	3	1	1	2	2	0	0	0	0	0	0	12	7.93
32024R178	Regulation (EU) 2024/1787 of the European Parliament and of the Council of 13 June 2024 on the reduction of methane emissions in the energy sector and amending Regulation (EU) 2019/942 (Text with EEA relevance)	0	1	0	3	6	1	1	0	0	0	0	0	0	0	12	7.71
32016R203	Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC	0	1	5	3	1	0	2	0	3	2	0	0	0	0	17	7.64

Figure 14 Example comparison of legislative texts

## 4.4 Using Generative AI effectively

Public servants and the general public can use large language models (LLMs) to better understand and apply EU regulation by translating complex legal language into accessible summaries, answering questions in plain terms, and offering relevant examples tailored to specific use cases. For civil servants, LLMs can support policy drafting, compliance checks, and interdepartmental coordination. This is a more intuitive way of finding and applying information than using a conventional search engine under the assumption that a user has a proper frame of reference (domain specific knowledge).

In contrast to the fast insight at glance that powerful tools like LLM's deliver they have some known disadvantages, especially when used in sensitive or complex domains like law or public policy, such as:

- **Hallucinations (Generating Incorrect Information);** LLMs can confidently generate plausible-sounding but false or misleading statements, known as "hallucinations." This is especially risky when users assume the model is always factual.
- **Lack of Up-to-Date Knowledge;** Unless connected to real-time data sources, LLMs are only as current as their last training cutoff. This can be problematic in fast-evolving fields like regulation, where new laws or amendments may not be reflected.
- **Lack of True Understanding or Reasoning;** LLMs predict text based on patterns, not true comprehension. They may miss legal nuance, implicit logic, or domain-specific reasoning unless paired with more structured systems (like knowledge graphs or rule-based engines).
- **Explainability and Trust Issues;** Outputs may be hard to trace or justify, especially when the model doesn't cite sources or explain its reasoning. This lack of transparency can undermine trust—particularly in legal, medical, or public-sector use cases.
- **Bias and Fairness;** Models can inherit and even amplify biases present in their training data. This can lead to unfair, discriminatory, or politically skewed outputs, especially if not carefully audited or fine-tuned for fairness.
- **Data Privacy and Security Risks;** If not properly safeguarded, LLMs may memorize and reproduce sensitive training data, or inadvertently leak confidential inputs, raising concerns around GDPR compliance and ethical use.
- **Dependence on Prompt Quality;** The accuracy and relevance of responses can vary significantly depending on how the question is phrased. This introduces variability and requires prompt engineering skills that not all users may have.
- **Computational Cost and Environmental Impact;** Running and fine-tuning large models can be resource-intensive, both financially and environmentally, especially at scale.

These challenges don't mean LLMs shouldn't be used—but they do highlight why they need to be paired with human oversight, external knowledge bases, domain-specific tuning, and robust governance frameworks. Therefore, we recommend and apply Knowledge Graphs in our solution.

A knowledge graph provides a structured, machine-readable representation of entities (like laws, institutions, sectors, or legal terms) and the relationships between them. When combined with an LLM, it acts as a layer of semantic logic and disambiguation that enhances the model's ability to reason, search, and respond with specificity and accuracy.

In this context, knowledge graphs add value in the following ways:

- **Precise Search and Navigation;** Instead of keyword-based search, the LLM is equipped with relevant information from the knowledge graph to ‘understand’ the meaning behind terms and navigate relationships. For example, if a user asks about "data protection in cross-border healthcare," the knowledge graph helps the model retrieve the correct directives, cases, and entities involved, even if the exact phrase isn't used.
- **Contextual Grounding;** The knowledge graph anchors the LLM in a well-defined, up-to-date context. This is critical when laws evolve, as the graph can maintain accurate links to versions, jurisdictions, and legal interpretations—ensuring the LLM doesn't hallucinate or generalize inappropriately.
- **Unambiguous Logic and Reasoning;** Legal and regulatory language often relies on formal logic—such as definitions, scopes, exceptions, and dependencies. A knowledge graph allows the system to apply rules and logic explicitly, which an LLM alone (being probabilistic) cannot always guarantee. This supports more trustworthy outputs when interpreting or applying rules.
- **Improved Formulation and Explanation;** When generating summaries, recommendations, or official responses, the LLM can use the knowledge graph to structure its explanations, cite authoritative sources, and follow domain-specific terminology consistently (xAI).

In essence, the knowledge graph acts as a domain specific logic-based backbone, while the LLM provides natural language flexibility and interaction. Together, they create a system that is both user-friendly and legally precise—ideal for high-compliance domains like EU regulation.

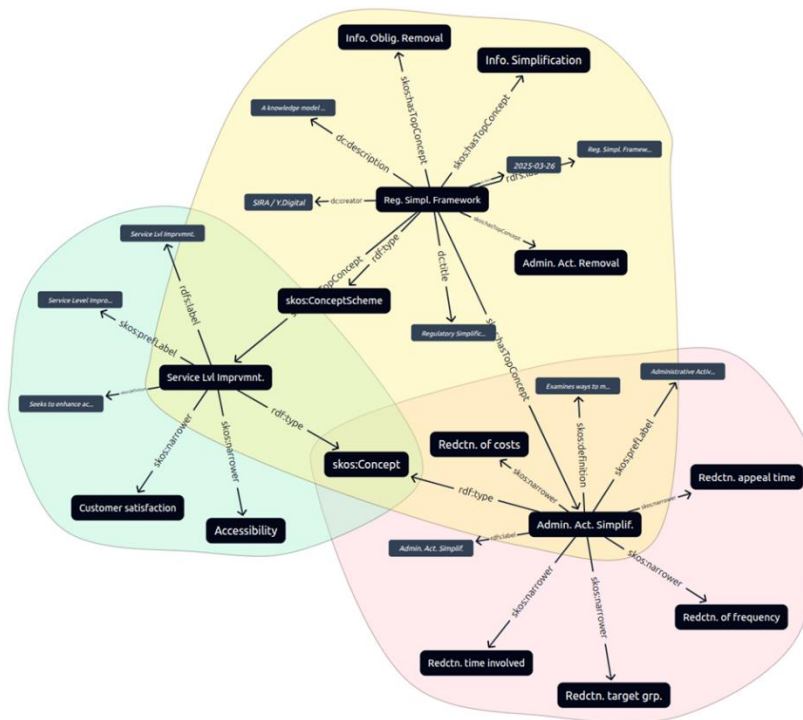


Figure 15 Example knowledge graph

## Technical challenges

During the development of the AI tool, technical as well as data-related obstacles have arisen. On the one hand, keeping the generative AI parts of the solution under control remains challenging and (very) long textual input can surpass the processing limits of these solution components. . On the other hand, unclarity and missing implementation details in the legislative texts can make it difficult for the tool to extract the necessary information to analyse regulatory burden. In this section, we address both technical and data-related issues and outline possible solutions.

### Preventing hallucinations and inaccuracies

An important design decision for the architecture of the AI tool is the central role of expert knowledge modelling, with the goal of relevant and accurate output. Even when equipped with this knowledge in the form of instructions and guardrails, the employed generative AI models can occasionally leave their intended domains of operations and produce unwanted output. Examples range from misspelling an information obligation category (e.g. using a plural instead of a singular or vice versa) when extracting the obligation overview table to misclassifying a given obligation into a related but incorrect category or making up entirely new categories of information obligations that were not specified in the training data.

While future LLMs will undoubtedly improve on their ability to closely follow instructions and limit hallucinations, this risk can also be mitigated in other ways, e.g. with the following measures:

- Providing more training data examples for the different heuristics dimensions of regulatory burden will lead to more complete and more accurate source text annotations. In turn, this means that the LLM will not have to come up with its own guess at an obligation classification where the annotation mechanism might have missed the obligation altogether. Furthermore, more training data examples will result in an improved ability of the annotation mechanism to differentiate between different types of obligations, making misclassifications in the LLM less likely.
- Implementing post-processing logic through further knowledge modelling can help achieve a high accuracy when classifying information obligations in legislation and extracting their details from the source texts. This may, for example, take the form of rejecting LLM hallucinations concerning obligation categories or and submitting the relevant parts of the input texts to the LLM for re-evaluation. It is also possible to implement more complex logic to check the model output and store it in the knowledge graph. For instance, decision rules concerning obligation classification using other extracted obligation characteristics could be used when the annotation pipeline gives ambiguous results.

The common denominator of the measures described is that the shortcomings of generative AI can be mitigated by knowledge modelling. This aligns well with the architectural principles behind the AI tool, which place domain-specific expert knowledge at the heart of the application.

### **Dealing with very long input**

When processing very long texts with LLMs, one may run into their technical limitations. Current models are often not able to process more than roughly 100,000 words of English text and do not give outputs longer than roughly 3,000 words. While these limits are usually unproblematic when the focus of evaluation is a single piece of legislation, it is not possible to analyse many texts simultaneously in this manner. Again, these limitations will likely shift for future LLMs, but it is also possible to tackle them through summarisation: when comparing multiple pieces of legislation for overlapping regulatory burden, the approach chosen here is to let the AI tool summarise the information obligations in each piece of legislation separately in a first step, after which the results of these analyses are then processed for a second time to detect overlap. Next to solving the problem of long inputs this strategy also has the benefit of better verifiability and interpretability: the intermediate summaries of information obligations in the input legislation can be made available to the user for validation purposes and make the tool's reasoning more transparent. In turn, this transparency realises the human-in-the-loop design principle and makes it possible to evaluate and improve.

### **Data-related challenges**

When evaluating regulatory burden in EU legislation with the AI tool, a common problem that arises is missing information or unclarity in the source texts. While the tool's methods are suited to extract explicit information obligations from the source texts, it should not be used to "fill in the gaps" in their absence to avoid LLM hallucinations. In fact, the LLM is explicitly instructed to only extract explicitly available information to safeguard accuracy.

In practice, this means that some legislative texts cannot be exhaustively evaluated without considering additional information. For instance, a crucial part of calculating the administrative costs of an obligation is the determination of the obligation frequency. This information may not be specified in the source text of a directive containing the obligation, but only in its national implementations or even their explanatory notes. Consequently, these additional source texts are necessary in such a case to perform the calculation of administrative costs (which then also apply to the corresponding national levels).

Information to analyse administrative burden may also be missing entirely from legislative texts. For example, when trying to estimate administrative costs, the number of affected businesses is a necessary parameter of the calculation. In these cases, the tool may be extended to interact with the user to provide the information where necessary, or references to relevant knowledge bases (e.g. Eurostat) may be integrated into the knowledge graph that is part of the training data of the tool. It can then be extended to retrieve information necessary for the analysis that is not explicitly provided in the source texts from these knowledge bases.

## **4.5 Outlook**

Given the observations made and challenges faced during the development of the AI tool, we can make some suggestions concerning the next steps that can be taken to further evolve it.

### **Training data for accuracy and more sophisticated use-cases**

Expert knowledge that is implicitly used for evaluating regulatory burden in legislation is already part of the current model in the form of information obligation heuristics and their examples. While expanding these existing knowledge models leads to more accurate results and already enables post-

processing checks, there is likely a lot more implicit knowledge that experts use in their analyses. Making this knowledge available to the tool will further improve accuracy and relevancy of the tools outputs and may enable more sophisticated use cases. For example, the AI tool's functionalities may be extended to provide concrete suggestions on how to reduce regulatory burden in a given legislative text. A common way to represent this kind of information in a machine-readable way is through domain-specific taxonomies and ontologies in the form of knowledge graphs as shown in figures 15 and 16. Extending the tool's capabilities to process these forms of training data and derive evaluation logic from it yields a powerful way to broaden its possible use-cases.

### User interaction to counter uncertainty

As mentioned before, missing information or unclarity in source texts can lead to incomplete assessments. Here, the human-in-the-loop principle can be further expanded upon: while it is possible to try to include as much information as possible a priori in the training data, a more flexible approach might be to enable the user of the tool to provide, on demand, the information that it needs to complete its analyses.

For instance, a conversational agent-like interface may be developed in which the tool asks the user for specific data until the evaluation can be completed. In this way, the user can also request specific types of analyses rather than always making use of the full pipeline. While manual interventions like these reduce the time efficiency of the tool, they may be, for example, interesting in an ex-ante situation when parameters of the draft legislation are not yet fixed and can be experimented with in this manner (see also Step 4).

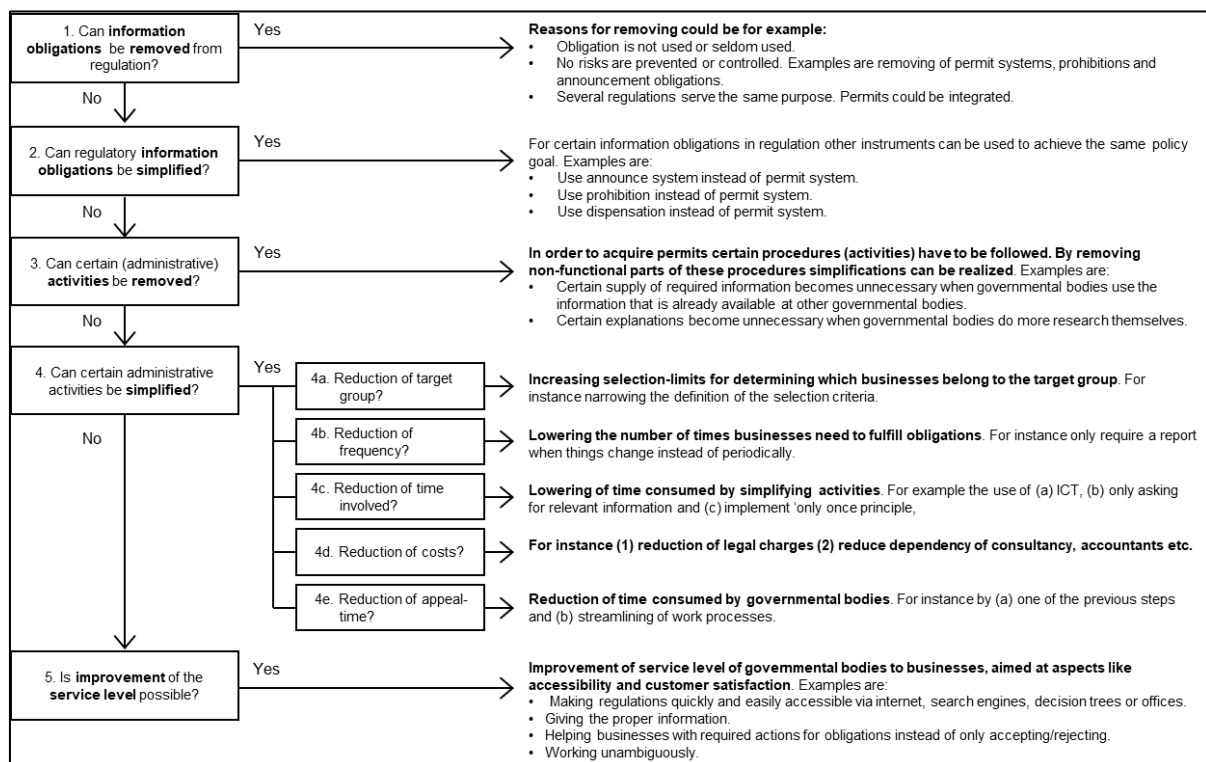


Figure 16 Example visualization of an ontology in a knowledge graph

## **Better generative AI components**

The market for generative AI technologies is evolving at a very fast pace. While general models become more adept at, e.g., following instructions, semantic tasks or reducing hallucinations, more specialised agentic models emerge, catered to specific domains in which they excel. The AI tool may benefit from these developments in that the general purpose LLM that is used to process the legislation texts may be replaced by one that is specifically trained for applications in the legal domain. Higher reliability on the part of the LLM could then reduce the amount of training data needed to produce high-quality results. From a technical perspective, the modular architecture of the tool makes adopting these new models comparatively easy. However, this should not be taken as a signal to abandon the knowledge modelling component of the tool in the long run. It remains essential to give guidance and reduce the black box characteristics of the system. It remains essential to give guidance and reduce the black box characteristics of the system. In our architecture the AI-Kernel holds all domain specific logic and boundaries and allows for multi-model integration and exchange.

## **Standardised RB-interface for member states**

The RB-Index is a Eurlex centric system. To accelerate and drive the adoption of the application we recommend to create an interface to which member states can connect their datasets in a standardised and easy manner. The interface would give descriptions, conventions and some simple tooling to model, adapt and integrate your national dataset so you can use the RB-Index and related instrument. Components of the solution could hold things like e.g. the Eurlex National Implementation Measures<sup>30</sup>.

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<sup>30</sup> Eurlex National Implementation Measures <https://dev.eui.eu/library/eur-lex-survey-on-national-implementing-measures-nim-consultation/>



## 5. Recommendations

### 5.1 Concluding remarks

Effectively reducing regulatory burden in the EU requires addressing a fundamental issue in the current approach: the **overreliance on ex-ante assessments to estimate regulatory impacts**. These predictions are often unreliable because EU legislation frequently leaves significant room for implementation by (EU) agencies or Member States, creating a gap between anticipated burdens and actual outcomes in practice. This disconnect, highlighted in various impact assessments, has been identified as a major flaw, including in critiques of the CSDD Directive. As a result, businesses face significant uncertainty and find it difficult to prepare for compliance, while the true regulatory burden often only becomes clear after implementation<sup>31</sup>.

Addressing regulatory burdens requires a restructured legislative process where it is clear from the outset how regulations will be implemented in practice. This necessitates **the early involvement of implementing agencies and regulators in the legislative process**. To ensure EU policy objectives are met, phased policy instruments should be used to incentivise participation by leading businesses. This would direct public funding more effectively toward target groups (businesses) rather than costly consultancy and research firms.

**AI tools can play a crucial role** in supporting this process by identifying and analysing regulatory obligations and their impacts. For existing regulations (older than 4-6 years), reducing burdens requires a focus on the operational level: examine obligations as experienced by businesses. Targeted research into specific obligations can help define best practices. To engage stakeholders effectively, this approach can be embedded within a clear and appealing program, using models like the SME indicator company approach to drive meaningful and measurable reduction targets in regulatory burdens.

To effectively address regulatory burden, a **strategy is required that both prevents unnecessary burden from new legislation and focuses on reducing existing burdens**. This calls for an innovative, adaptive approach to EU legislation that prioritises clarity, measurability, and stakeholder engagement. Below, the recommendations are structured according to the **four preconditions for an effective EU Regulatory burden reduction program**.

### 5.2 Recommendations

#### A. **Develop an AI-supported Regulatory Burden Index as the next step in Better Regulation and EU's ambition**<sup>32</sup>

The European Union lacks a **fast, structured, and comparable** method to assess regulatory burden across EU legislation and its national implementation. The preliminary version of the Regulatory Burden Index developed in this pilot is an analytical and preventive tool that **quantifies and evaluates the regulatory burden** of both existing and proposed legislation by integrating **AI-driven analysis with expert knowledge**.

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<sup>31</sup> SOLVIT and also FIN-NET, and Your Europe empower people and businesses to fully use their rights in the single market.

<sup>32</sup> Lisbon European Council, 23 and 24 March 2000 Presidency Conclusions:  
[https://www.consilium.europa.eu/uedocs/cms\\_data/docs/pressdata/en/ec/00100-r1.en0.htm](https://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/ec/00100-r1.en0.htm)



A successful implementation requires:

- **AI-based analysis of regulatory texts** – Automating the extraction and classification of regulatory obligations from EU legal texts to enable real-time burden assessment.
- **Heuristics and metrics** – Translating regulatory burden expertise into quantifiable rules and indicators that allow structured comparison of different regulations.
- **Pilot testing on all levels of (EU) legislation** – Validating the index by applying it to real legislative texts to ensure practical applicability and refine measurement accuracy.
- **Integration into the EU and Member States policymaking process** – Embedding the RBI in Impact Assessments and Regulatory Fitness Checks (REFIT) to provide structured, data-driven insights on regulatory burdens before legislation is enacted.

The approach with the RBI would enable policymakers and decision-makers to gain real-time insights into the expected regulatory impact at any stage of the EU or national decision-making process. It would also provide concrete suggestions to reduce burdens while maintaining societal and policy objectives.

It is recommended that this AI tool be developed at the EU level and made available to Member States. This would ensure that all Member States can assess the expected effects of EU regulation in a consistent and comparable manner.

The **EU's ambition for Europe to become the most dynamic and competitive knowledge-based economy** in the world. However, regulatory complexity and administrative burdens continue to hinder innovation, investment, and growth, particularly for SMEs. The Regulatory Burden Index represents a possible **next step in realizing the EU ambition by making regulatory policymaking more transparent, data-driven, and business-friendly**.

## **B. The SME Indicator Company Approach: A targeted and measurable strategy for reducing regulatory burden**

The rapid introduction of new regulations has led to a lack of reliable data on the actual costs of existing legislation. Given the vast number of rules and the diversity in national implementation, conducting a comprehensive baseline measurement for all EU regulations is neither realistic nor efficient. To address this challenge, a more targeted approach is required, one that provides sector-specific insights while enabling comparisons across Member States.

### **A Sector-Based, Comparative Approach**

The SME Indicator Company method offers a structured and efficient way to assess and reduce regulatory burdens. Instead of large-scale baseline measurements, this approach examines sector-specific regulatory burdens by hypothetically placing representative companies, such as a hotel or manufacturing business, within different Member States. This enables comparative insights, highlighting best practices and inefficiencies in regulation.

Consultations with reference companies ensure that these indicator firms accurately reflect sectoral realities in terms of size, activities, and compliance challenges. By analysing how the same EU regulations are applied across different countries, this method provides a business-centric perspective on regulatory fragmentation and inconsistencies in implementation.

### Measurable Reduction Target

To ensure a systematic and impactful burden reduction, a reduction target of 20-25% per indicator company is proposed, with a baseline set as of July 1, 2025. This enables concrete reduction proposals, aligned with the Standard Cost Model principles. Additionally, increases in regulatory burdens should be quantified and offset at the indicator company level to maintain a net reduction target<sup>33</sup>.

By identifying which Member States implement EU regulation most efficiently, the EU can leverage best practices to encourage more effective and streamlined regulatory implementation across the Single Market. This contributes to a more predictable business environment, reducing unnecessary compliance costs for SMEs.

### AI-Powered Regulatory Insights

AI tools, such as RBI, can further enhance the efficiency of this approach by analysing regulatory overlaps and inconsistencies between EU legislation and national implementations. The only -once principle could also be applied at the Member State level, preventing duplicative data requests from businesses and ensuring a more streamlined compliance process.

By aligning ex-post evaluations with ex-ante assessments, this method creates a cohesive regulatory framework that minimizes unnecessary burdens. Furthermore, structural use of an Omnibus approach allows for interim regulatory adjustments, ensuring that SMEs experience tangible relief without waiting for lengthy legislative cycles.

### A Focused and Scalable Approach to Burden Reduction

The SME Indicator Company principle is designed to achieve broad regulatory impact: when burdens for indicator companies are reduced, all businesses subject to the same obligations benefit. By selecting indicator companies across multiple sectors, a large share of SME regulatory burdens can be systematically addressed. This approach ensures that reduction efforts focus on EU regulation with the highest business impact, allowing for efficient, measurable, and targeted regulatory burden reduction across the EU.

### Some suggestions for Indicator Companies by Sector with SBI/NACE Codes

Sector	Explanation	Specific EU Legislation	NACE Codes
Digital Economy and IT Services	The digital transformation imposes stricter requirements on data management, cybersecurity, and artificial intelligence. Companies face new obligations under the GDPR and Digital Services Act.	General Data Protection Regulation (GDPR), Digital Services Act (DSA), AI Act	62 (Computer programming, consultancy and related activities), 63 (Information service activities)

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<sup>33</sup> In the indicator company project, the analysis focused solely on the actual compliance costs of existing legislation. Adjustment costs were not considered within the scope but can be added.

Sector	Explanation	Specific EU Legislation	NACE Codes
Agriculture and Food Production	Agricultural and food companies face significant regulatory burden due to the Farm to Fork strategy and regulations on food safety, pesticides, and climate measures.	Common Agricultural Policy (CAP), Farm to Fork Strategy, EU Pesticides Regulation	01 (Crop and animal production, hunting and related service activities), 10 (Manufacture of food products)
Transport and Logistics	This sector is heavily regulated by EU legislation related to emission reductions, the greening of transport and infrastructure, and logistical optimisation within the single market.	Euro 7 Emission Standards, Trans-European Transport Network (TEN-T), Sustainable and Smart Mobility Strategy	49 (Land transport and transport via pipelines), 52 (Warehousing and support activities for transportation)
Construction and Infrastructure	The construction sector faces significant obligations under the green transition, including regulations for energy efficiency, the circular economy, and sustainable materials.	Energy Performance of Buildings Directive (EPBD), Construction Products Regulation (CPR), Circular Economy Action Plan	41 (Construction of buildings), 42 (Civil engineering)
Retail and E-commerce	Retail and e-commerce businesses are significantly impacted by regulations on consumer rights, digital services, and sustainability requirements for packaging.	Digital Services Act (DSA), Packaging and Packaging Waste Regulation, Consumer Rights Directive	47 (Retail trade, except of motor vehicles and motorcycles), 49 (Postal and courier activities for e-commerce)
Textile and Fashion Industry	The textile sector faces stricter rules due to a focus on sustainability, circular economy requirements, and waste management, including mandatory product labelling and recycling.	EU Strategy for Sustainable and Circular Textiles, Waste Framework Directive, Green Deal	13 (Manufacture of textiles), 14 (Manufacture of wearing apparel)
Chemical Industry	Small chemical companies face higher burdens due to stricter obligations for reporting substances, registration requirements, and compliance with environmental rules.	REACH Regulation, Chemicals Strategy for Sustainability, CLP Regulation (Classification, Labelling, and Packaging)	20 (Manufacture of chemicals and chemical products), 21 (Manufacture of basic pharmaceutical products and pharmaceutical preparations)
Healthcare and Pharmaceuticals	The healthcare and pharmaceutical sectors are impacted by complex rules on product safety, data protection, and new technologies.	EU Medical Devices Regulation, GDPR, AI Act	21 (Manufacture of basic pharmaceutical products and pharmaceutical preparations), 86 (Human health activities)
Tourism and Hospitality	The tourism and hospitality sector is facing mandatory sustainability measures, energy efficiency requirements, and consumer protection laws that increase operational burdens.	Energy Efficiency Directive (EED), Consumer Rights Directive	55 (Accommodation), 56 (Food and beverage service activities)

### C. Evidence-informed legislative Development for a predictable and business-friendly EU Regulatory Framework

To mitigate the uncertainty and cumulative burdens caused by the rapid introduction of new EU legislation, particularly in the green and digital transitions, a more **evidence-informed legislative process** is essential. New regulations should only take **full effect once all obligations and implementation plans** are clearly defined at the operational level.

#### Key Elements of an adaptive approach:

- Interim facilitative measures such as development programs and subsidies should support businesses, particularly SMEs, by allowing them to co-develop and test implementation strategies in collaboration with frontrunner companies across Member States.
- Thorough cumulative burden analysis should be conducted to prevent regulatory overlap and inconsistencies, ensuring alignment with business processes, data flows, and EU standards.
- AI-driven risk assessments can help predict regulatory burdens (trickle-down effect) and propose alternative solutions to minimize compliance costs.
- Simultaneous implementation across all Member States should be mandatory to ensure a level playing field, avoiding fragmented enforcement and competitive disadvantages.

By embedding **clarity, alignment, and technological support** into the legislative process, this approach will foster **predictable, business-friendly regulations**, reducing unnecessary burdens and strengthening SME competitiveness across the EU. A similar approach has already been applied in the development of the Carbon Border Adjustment Mechanism (CBAM), as illustrated in Case 6 in Annex I.

### D. Strengthening Uniform Implementation for a Competitive EU

Inconsistencies in the implementation of EU legislation remain a key challenge, undermining the level playing field essential for global competitiveness and productivity. The Draghi report emphasized the need for greater unity at the European level to address this issue.

To achieve this, greater use of regulations rather than directives is recommended where maximum harmonization is justified, minimizing implementation differences between Member States. In some cases more freedom is needed for Member States (such as for the Nature Restoration Regulation, which should have been a directive due to widely diverging situations in Member States). The essence is that the legislator should carefully consider what instrument is the right approach in a specific case. And this should not only be a political argumentation<sup>34</sup>.

To prevent market fragmentation, the EU must actively pursue harmonized implementation through the following principles:

- **One EU Rule In, 27 National Rules Out:** Where the EU adopts a regulation, it should fully replace national laws to eliminate inconsistent national implementations. This principle ensures that one EU rule removes 26 national variations, creating a single, predictable regulatory framework across the Single Market. This should apply only to regulations, ensuring uniform obligations for businesses without additional national requirements.

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<sup>34</sup> In the case of the CSDDD political considerations lead to the choice for a directive, whereas the content demanded for a Regulation.

- **Monitoring and Promoting Best Practices:** The EU should actively track and compare implementation across Member States to identify the most efficient regulatory practices. Best practices should be promoted as the standard and, where necessary, mandated to ensure that regulatory implementation remains consistent and effective.

Additionally, an enforcement mechanism should be established to ensure compliance with reduction targets and the uniform implementation of EU legislation. This could include actively promoting or mandating identified best practices across Member States. Or if Member States fail to implement regulations uniformly, the EU should enforce harmonization by applying **mutual recognition**: If a company complies with an EU obligation in one Member State, it should automatically be recognized in all others.

This mechanism pressures Member States to align implementation and reduces barriers for businesses operating across borders. Allowing businesses to choose the implementation of any Member State forces governments to adopt efficient and transparent regulatory approaches, fostering fair competition.

By embedding these enforcement principles into EU policymaking, regulatory burdens can be significantly reduced while maintaining policy objectives. This approach ensures a predictable, business-friendly regulatory environment, strengthens competitiveness, and reinforces the Single Market as a foundation for economic growth.

## Annexes

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## Annex 1 Cases

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### Case 6. Regulation on the Carbon Border Adjustment Mechanism (CBAM)

The CBAM is a European Union instrument aimed at assigning a fair price to the carbon emissions embedded in the production of carbon-intensive goods imported into the EU.<sup>1</sup> This mechanism, the world's first such levy, encourages cleaner industrial production in non-EU countries and helps prevent 'carbon leakage', where production relocates to countries with less stringent environmental regulations. The CBAM transitional (pilot) period started 1 October 2023.

The following goods are currently in scope of the CBAM: iron and steel, cement, fertilisers, aluminium, electricity, and hydrogen. The scope will additionally include certain precursors, and a limited number of downstream products (not yet chemicals and polymers).

#### Impact

In the CBAM definitive regime (as of 2026), the following actions are required for the covered companies importing goods:

1. To register with national authorities, where they can also buy CBAM certificates. The price of the certificates will be calculated depending on the weekly average auction price of EU ETS allowances expressed in €/tonne of CO<sub>2</sub> emitted.
2. To declare the emissions embedded in their imports and surrender the corresponding number of certificates each year.
3. To prove that a carbon price has already been paid during the production of the imported goods so that the corresponding amount can be deducted. During the transitional period, importers of CBAM goods have been required to submit quarterly reports with the quantities



of CBAM goods imported (specified per country of origin per production site, the embedded greenhouse gas emissions thereof) and, If applicable, the carbon price due in the country of origin.

As the reported experience has shown, 80% of the companies covered by Carbon Border Adjustment Mechanism CBAM are responsible for only 3% of emissions. And thus 20% of companies for 97%. As was recently stated by EU Climate Commissioner Wopke Hoekstra by February 2025.<sup>2</sup>

### Improvements

Based on this recent experience, the scope of the CBAM will be adapted. In 2025, the European Commission proposed exemptions for ‘the vast majority’ of companies covered by the CBAM, on the grounds that they produce only 1% of the targeted emission reductions in the scheme. The proposal aims to reduce administrative burdens by applying the regulation only to companies importing more than 50 tons of goods annually (a mass-based threshold) exempting the vast majority of importers from the levy.

The move, due to be proposed as part of a package of measures to cut red tape for businesses, would drastically relieve approximately 180,000 importers covered by the EU's carbon border fee. These adjustments aim to reduce administrative burdens and simplify compliance, while still ensuring that more than 99% of the targeted emissions remain covered under CBAM.

The first two Omnibus packages focus on also on strengthening the carbon border adjustment mechanism, and improving access to European investment programmes. These proposals will now be reviewed by the European Parliament and the Council.

1. [https://taxation-customs.ec.europa.eu/carbon-border-adjustment-mechanism\\_en](https://taxation-customs.ec.europa.eu/carbon-border-adjustment-mechanism_en) EU-Regulation on the Carbon Border Adjustment Mechanism
2. [www.reuters.com/markets/europe/eu-exempt-most-companies-carbon-border-levy-draft-shows-2025-02-24](http://www.reuters.com/markets/europe/eu-exempt-most-companies-carbon-border-levy-draft-shows-2025-02-24) Reuters, February 24, 2025

## Case 7. Reach's increasing regulatory burden

Since 2007, the regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is an European legislation aimed at protecting human health and the environment from the risks that chemicals pose.<sup>1</sup> It not only applies to chemical substances used in industrial processes, but also in ordinary products such as cleaning products, paints, clothes, etc.

The REACH regulation dictates that companies need to register the substances they work with. To do so, they have to “work together with other companies who are registering the same substance.” The core idea behind this is that registration enables better regulation of chemical substances.<sup>2</sup> Since 2007 the regulation has been amended multiple times. One of the most recent changes concerns the adjustment of information requirements for the registration of chemical substances as from early 2022.

### Impact

According to ECHA, the European Chemicals Agency, the regulation impacts “a wide range of companies across many sectors, even those who may not think of themselves as being involved with

chemicals.”<sup>3</sup> Responsibilities prompted by the regulations will to at least some extent impact manufacturers, importers, and downstream users.

By 2018, the European Commission reported that approximately €4.8 billion had been spent on around 90,000 REACH registrations, averaging €54,000 per registration.<sup>4</sup> These costs are constituted by the (complexity of) the substance identity, information requirements, ECHA fees and invested time. It is estimated that it takes from “20 to 40 hours to submit a registration dossier for a previously registered substance.”<sup>4</sup> This time is expanded in cases when the substance is not yet registered under REACH.

As of 2022, an upward adjustment of REACH information requirements has introduced additional and stricter data requirements for registering chemical substances causing higher testing costs and shorter reporting time.

### The Netherlands

In the Dutch context, 43.700 SME’s were expected to be impacted by the regulation to some extent.<sup>5</sup> A research conducted by Panteia, based on a sample of 36 impacted SME’s, mapped out the following compliance costs:

- Gathering information about REACH (message 17): 33 out of 36 companies incurred costs, with an average cost of €3,300 per company (or €3,000 including companies with no costs).
- Preparing an SDS and eSDS (message 6): 28 out of 36 companies incurred costs, with an average cost: €12,000 per company (or €9,000 including companies with no costs).
- Reading and interpreting SDSs for internal use (message 11): 21 out of 36 companies incurred costs with an average cost of €3,500 per company (or €2,000 including companies with no costs).
- Implementing SDSs in the workplace (message 7): 18 out of 36 companies incurred costs with an average cost of €3,300 per company (or €1,500 including companies with no costs).
- Purchasing or adapting ICT/data management systems (message 16): 15 out of 36 companies incurred costs with an average cost of €4,500 per company (or €1,800 including companies with no costs).
- Labeling as a result of REACH (message 14): 14 out of 36 companies incurred costs with an average cost of €9,000 per company (or €3,500 including companies with no costs).

### **Improvements**

A Eurochambres report presents 60 recommendations aimed at reducing regulatory burdens. Among these, there is a proposal to enhance the regulatory framework for the REACH regulation:<sup>6</sup>

- Frequent updates and amendments to chemical regulations require companies to constantly track and implement changes, which demands significant resources. To address this, Eurochambres suggests streamlining and expediting the approval process while adjusting information requirements to a more manageable level.
- The current authorization process is complex, time-consuming, and costly. Instead of requiring individual authorisation for each application, Eurochambres advocates for a

restriction procedure that includes broad, general exemptions, making compliance more efficient.

1. <https://echa.europa.eu/regulations/reach/understanding-reach>
2. <https://www.rivm.nl/en/reach>
3. <https://op.europa.eu/en/publication-detail/-/publication/bbf2a250-c996-11eb-84ce-01aa75ed71a1/language-en> Study on the impacts of the 2018 REACH registration deadline
4. <https://reachcompliance.io/guidance/what-is-the-cost-of-an-eu-reach-registration/>
5. [https://www.eerstekamer.nl/overig/20131016/impact\\_reach\\_op\\_mkb](https://www.eerstekamer.nl/overig/20131016/impact_reach_op_mkb) – Panteia (2013) p. 83
6. <https://www.eurochambres.eu/publication/eurochambres-input-on-most-burdensome-proposals-for-regulatory-intervention/>

## Case 8. NIS-2 Directive: new rules on cybersecurity of network and information systems

The NIS2 Directive stands for Network and Information Security Directive 2. It constitutes a renewed European directive for cybersecurity with a deadline for national implementation last October 2024. The NIS2 is the successor to the original NIS Directive (2016) and aims to strengthen the digital resilience of essential and important sectors within the EU.

Among the most important aspects of the new directive are the expansion of sectors to which it applies, stricter security requirements, stricter reporting obligations, heavier sanctions for non-compliance, more inspection, and liability of directors.<sup>1 2</sup>

### Impact

While companies acknowledge the value of the NIS2 directive, they also express concerns about the implementation, especially in terms of associated costs.<sup>3</sup> 68% percent of companies included in research expect that greater efforts will be needed to comply with the NIS2-directive.

A report from the European Union Agency for Cybersecurity (ENISA, 2024) highlights the regulatory impact of the NIS-2 directive on businesses.<sup>4</sup> Key findings include:

- Companies now allocate 9.0% of their IT budgets to information security, marking a notable rise of 1.9 percentage points compared to the preceding year.
- To meet NIS-2 requirements, 89% of organizations anticipate the need for additional cybersecurity personnel, with the greatest demand in cybersecurity architecture and engineering (46%) and cybersecurity operations (40%).
- A significant portion of cybersecurity staff (76%) lack certified training necessary for NIS-2 compliance, indicating the need for additional training of staff.
- Many organizations expect their cybersecurity budgets to increase, either as a one-time adjustment or on a permanent basis. However, 34% of SME's may struggle to secure the necessary additional funding.

Currently, cybersecurity incidents must be reported under NIS-2 within 24 hours, with more detailed reports due within 72 hours. Furthermore, the GDPR and the CRA also require reports of data breaches and incidents. Both the different timing and different bodies to whom should be reported are confusing to businesses.<sup>6</sup> Additionally, non-compliance with NIS-2 could result in substantial fines for companies, with some enterprises facing penalties of up to € 10 million or 2% of the yearly turnover.<sup>5</sup>

## Improvements

A report by Business Europe (January 2025) concluded that reporting obligations of cybersecurity incidents are confusing and excessive. It addresses the regulatory burden of EU policies, mapping the 68 most pressing burdens and offering proposals to reduce them.<sup>1</sup> The Cybersecurity legislation, including the NIS-2 regulation, is part of this report.

1. <https://ccb.belgium.be/nl/document/de-nis2-richtlijn-wat-betekent-dit-voor-mijn-organisatie>
2. <https://www.digitaleoverheid.nl/overzicht-van-alle-onderwerpen/nis2-richtlijn/>
3. <https://www.ictmagazine.nl/nieuws/zorgen-bij-bedrijfsleven-om-impact-nis2/>
4. [https://www.enisa.europa.eu/sites/default/files/2024-11/CSPA%20-%20NIS%20Investments%20-%202024\\_0.pdf](https://www.enisa.europa.eu/sites/default/files/2024-11/CSPA%20-%20NIS%20Investments%20-%202024_0.pdf)
5. <https://eur-lex.europa.eu/eli/dir/2022/2555>
6. [https://www.buinesseuropa.eu/sites/buseur/files/media/reports\\_and\\_studies/2025-01-22\\_buinesseuropa\\_mapping\\_of\\_regulatory\\_burden.pdf](https://www.buinesseuropa.eu/sites/buseur/files/media/reports_and_studies/2025-01-22_buinesseuropa_mapping_of_regulatory_burden.pdf)

## Case 9. SMEs withdraw due to complex procurement rules

Every year, approximately €2 trillion, or 14% of the EU's gross domestic product, is spent on public procurement.<sup>1</sup> European procurement law aims to remove barriers in the EU internal market and enhance competition within the internal market. Directive 2014/24/EU, known as the 'classic sectors directive', includes rules regarding public procurement for (construction) works, supply of goods, and provision of services.<sup>2</sup>

The European procurement directives focus on public contracting authorities that award contracts to businesses for these works, goods or services. The objective is for governments to procure transparently and effectively at the best price-quality ratio while ensuring that businesses have a fair and equal opportunity to secure contracts.<sup>3</sup> Some Member States experienced delays in transposing the directive into national law, leading to inconsistencies in its application.

## Impact

In 2023, the ECA evaluated Directive EU2014/24, which has been revised in 2014. The ECA concluded that the implementation has not yet had a demonstrable effect.<sup>4</sup> On the contrary:

- *Surveyed bidders and contracting authorities indicated that public procurement procedures still impose a significant administrative burden and have not been significantly simplified since 2011.*
  - More than half reported that lengthy procurement procedures discouraged companies from participating in public tenders. The procedures are perceived as too complex and less flexible than those in the private sector.
  - Data analysis by the ECA showed that current procedures take significantly longer than a decade ago. The total decision-making period, the time until the award of the contract (excluding appeal procedures) against award decisions, increased from 62.5 days in 2011 to 96.4 days in 2021.
- *The participation rate of small and medium-sized enterprises (SMEs) in such procedures has not increased significantly.*

- Overall, ECA data do not show a general increase in SME participation, though the situation varies by Member state. Austria and Lithuania experienced an increase in participating SMEs, while Sweden and Finland saw a decline. In most other Member States, the number remained relatively stable. Research commissioned by the Dutch Ministry of Economic Affairs and Climate indicates that two-thirds of public contracts in the Netherlands are awarded to SMEs.<sup>5</sup>
- *Since publication rates remain low, transparency (a key factor in mitigating the risk of fraud and corruption) is negatively affected.*
- ECA data show that more than half of the 27 Member States consistently had a publication rate of less than 5% between 2011 and 2021, without improvement over time. Over 43% of respondents do not monitor this indicator.
- *Some objectives of the 2014 revision sometimes conflict with the overarching goal of ensuring competition in public procurement.*

The unnecessary application of European procurement procedures to contracts below the threshold values can lead to unnecessary administrative burdens and complexity. Therefore, it is crucial for contracting authorities to be aware of applicable national regulations and the degree of flexibility they have in awarding such contracts so that they can apply procedures that are proportional and appropriate for the specific contract.

### Improvements

The European Commission is currently conducting an evaluation of the European procurement directives, including Directive 2014/24/EU. This aims to assess whether the directives have effectively achieved their objectives, such as promoting competition in the internal market and simplifying and making procurement procedures more flexible.

1. European Court of Auditors (ECA), Dec. 2023. Special Report 28/2023: "Public Procurement in the EU – Decreased Competition for Contracts for Works, Goods, and Services in the Period 2011–2021" [www.eca.europa.eu/ECAPublications/SR-2023-28/SR-2023-28\\_NL.pdf](https://www.eca.europa.eu/ECAPublications/SR-2023-28/SR-2023-28_NL.pdf)
2. <https://eur-lex.europa.eu/legal-content/NL/TXT/?uri=CELEX:32014L0024>
3. <https://europadecentraal.nl/wp-content/uploads/2016/06/Notitie-implementatie-nieuwe-aanbestedingsrichtlijnen-in-de-Aanbestedingswet-juni-2016.pdf>
4. European Court of Auditors (ECA), Dec. 2023. Special Report 28/2023: "Public Procurement in the EU – Decreased Competition for Contracts for Works, Goods, and Services in the Period 2011–2021" [www.eca.europa.eu/ECAPublications/SR-2023-28/SR-2023-28\\_NL.pdf](https://www.eca.europa.eu/ECAPublications/SR-2023-28/SR-2023-28_NL.pdf)
5. <https://zoek.officielebekendmakingen.nl/kst-34252-25.html#ID-1115964-d36e997>

## **Annex II      Table of Abbreviations**

<b>ATR</b>	Dutch Advisory Board on Regulatory Burden (ATR)
<b>AI</b>	Artificial intelligence
<b>BR</b>	Better Regulation Program
<b>BAU</b>	Business-as-usual
<b>CAP</b>	Common Agricultural Policy
<b>CLP</b>	Classification, Labelling, and Packaging
<b>CSDDD</b>	Corporate Sustainability Due Diligence Directive
<b>CSRD</b>	Corporate Sustainability Reporting Directive
<b>DSA</b>	Digital Services Act
<b>EPBD</b>	Energy Performance of Buildings Directive
<b>EED</b>	Energy Efficiency Directive
<b>EESC</b>	European Economic and Social Committee
<b>ECHA</b>	European Chemicals Agency
<b>F4F</b>	Fit for Future
<b>GDPR</b>	General Data Protection Regulation
<b>GMOs</b>	Genetically modified organisms
<b>IAs</b>	Impact Assessments
<b>LLMs</b>	Large Language Models
<b>NVWA</b>	Netherlands Food and Consumer Product Safety Authority
<b>NIM</b>	Eurlex National Implementation Measures
<b>OIOO</b>	One-in One-out principle
<b>P</b>	Total costs of obligation calculated with Toolbox #58
<b>Q</b>	Number of business that have to comply
<b>REFIT</b>	Regulatory Fitness and Performance Programme
<b>RSB</b>	Regulatory Scrutiny Board
<b>SCM</b>	Standard Cost Model
<b>SMEs</b>	Small and medium-sized enterprises

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aligning with the observation that the current approach lacks sufficient control over actual regulatory burdens. Finally, the absence of robust ex-post evaluations exacerbates the gap between policy predictions and the real-world experiences of businesses.

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## European Economic and Social Committee

Rue Belliard/Belliardstraat 99  
1040 Bruxelles/Brussel  
BELGIQUE/BELGIË

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