

REPORT

# Better regulation, stronger Europe

– enhancing competitiveness  
for SMEs and startups

How reducing unnecessary regulatory burdens through a more systematic, consistent and integrated use of the Better Regulation Toolbox can strengthen EU competitiveness.



The Letta report *Much more than a market – speed, security, solidarity* points to great potentials for reducing regulatory burdens through a stronger and more stringent use of the Better Regulation Toolbox. This deep dive analysis aims to provide specific and impactful initiatives that can deliver just that.

In preparation of the analysis, surveys of more than 3,350 export-oriented SMEs in 11 EU countries (Austria, Belgium, the Czech Republic, Denmark, France, Germany, Ireland, Italy, Poland, Spain and Sweden) have been completed. Also, we have conducted multiple interviews with SMEs, a detailed literature survey and stakeholder consultations.

This report summarises the solutions and specific recommendations brought forward by the stakeholders. The work was commissioned by Amazon, and we are grateful for input from the Italian Confederation of Small and Medium-sized Enterprises (CONFAPI), the Austrian Federal Economic Chamber (WKO), Austrian Federal Ministry of Labor and Economy (BMAW), Austrian Startups, the Internal Market and Competitiveness Unit at the Permanent Representation of the Czech Republic to the European Union, the Czech Chamber of Commerce, the Association of Small and Medium-sized Enterprises and Crafts of the Czech Republic (AMSP), the Slovak Alliance for Innovation Economy (SAPIE), the Impact Assessment Unit at the Business Environment Improvement Department (Slovak Ministry of Economy), Comenius University in Bratislava, (Faculty of Management), Slovak Business Agency (SBA) and Crowdberry (the leading Slovak investment platform).

## 11 recommendations in the report “A path to prosperity, competitiveness and growth: putting SMEs back at the centre of the Single Market”

1. Adopt an ambitious Single Market Strategy.	Adopt a Single Market Strategy that clearly reinstates the Single Market at the forefront of the EU's integration project, green transition and innovation agenda.
2. Strengthen SOLVIT by establishing a Single Market Ombudsman in every EU Member State and commit SOLVIT to act more proactively on structural cases and to raise awareness.	Designate a Single Market Ombudsman (as head of or in collaboration with SOLVIT) in each Member State as a national, independent body with access to effective remedies. A network of Single Market Ombudsmen is to be set up under the auspices of the European Commission.
3. Conduct a data flow test of all existing and new EU regulation.	Implement a data flow test that acknowledges the supremacy of the principle of data protection in the EU but limits the risk of creating unjustified burdens when applying data protection rules.
4. Upgrade the European Semester to include recommendations on how to harmonise implementation of EU regulation and close the compliance gap.	Incentivise Member States to correctly apply and take political ownership of the correct application of EU rules, by integrating recommendations on closing the compliance gap and harmonising implementation of EU regulation into the European Semester.
<b>5. Strengthen the use of the Better Regulation Toolbox by integrating implementation into the design of new regulation and consistently respecting impact assessment requirements.</b>	<b>Put more weight on integrating implementation into the design of new regulations and avoid deviations from the requirement to make impact assessments.</b>
6. Map and remove regulatory barriers to trade in climate goods and services within the Single Market.	Map and remove regulatory barriers to trade in climate goods and services within the Single Market to accelerate decarbonisation by structuring market signals, incentivising innovation and reducing the price of new technologies.
7. Design the digital European product passport in a way that simplifies the circular work of businesses.	Introduce a well-designed Digital Product Passport based on stakeholder input, including SMEs.
8. Create a one-stop-shop to Member States' extended producer responsibility (EPR) systems.	Establish a truly harmonised approach to EPR: a centralised and up-to-date digital EPR one-stop-shop solution that would facilitate single EPR registration and reporting across all Member States at the product-level.
9. Create a single VAT ID and extend the VAT one-stop-shop.	Simplify VAT procedures by creating a single VAT ID in the EU and expanding the existing VAT one-stop-shop concept to cover all goods transactions.
10. Recognise digital labelling as a true substitute for physical labelling.	Bring EU labelling requirements to the digital era by providing manufacturers the option to choose whether to market their product digitally or physically.
11. Create conditions for the development of easy, fast, reliable and low-cost cross-border payments for both euro and non-euro payments.	Create a more competitive framework for cross-border payments to ensure that EU citizens have access to a diverse range of providers.

## Executive summary

Better EU regulation can enhance the competitiveness of European businesses by lowering compliance costs, enhancing transparency and reducing risks. The Letta report unequivocally calls for a stronger application of the Better Regulation Toolbox, advocating for its integration at the early stages of regulatory design and adherence to impact assessment requirements. This call echoes the voice of EU SMEs that shared their perspectives on regulatory barriers to doing business in the Single Market in preparation of the report *A path to prosperity, competitiveness and growth: putting SMEs back at the centre of the Single Market*, launched in April 2024.<sup>1</sup> Recommendation #5 in the Single Market report encourages EU policy makers to:

***“Strengthen the use of the Better Regulation Toolbox by integrating implementation into the design of new regulation and consistently respecting impact assessment requirements.”***

This report aims to provide specific and impactful initiatives that can deliver just that: reduce unnecessary regulatory burdens through a more systematic, consistent and integrated use of the Better Regulation Toolbox, especially for SMEs.

*why* The Single Market has been the engine of EU jobs, growth, and prosperity for over 30 years. Continued reduction of barriers and integration are essential for the Single Market to remain competitive and resilient in a more conflictual, volatile and complex world.<sup>2</sup> Chapter 1 presents survey results showing that European SMEs perceive regulatory differences across different Member States as the most critical barrier for them to do more business in the Single Market. These SMEs experience that regulatory barriers erode their competitiveness, leading to lower growth, higher costs and slower digitalisation.

*what* The analysis presented in Chapter 2 finds that there continues to be a potential for better regulation to reduce regulatory burdens. The research points to two main areas of improvement. *Firstly*, EU regulations should be designed in a way that makes them simpler to use and easier to comply with. EU regulations that cater for the needs of SMEs will reduce compliance costs, strengthen competitiveness and support innovation. *Secondly*, EU regulations should be designed in a way that ensures even and timely implementation. Less fragmentation and gold-plating enable SMEs to grow through the Single Market.

*how* EU policy makers have repeatedly put forward their commitment to reducing unnecessary regulatory burdens, and the Better Regulation Toolbox has the potential to help develop EU regulations that meet the desired policy objective while being targeted, effective, easy to comply with and with the least burden possible.

As it is often difficult for SMEs to point to specific initiatives that can reduce regulatory burdens, we have consulted stakeholders that in various ways represent SMEs, including business associations, innovation institutions, startup environments and national regulators engaged in Single Market reforms.

Stakeholders point to the nine specific initiatives that could strengthen the use of the Better Regulation Toolbox and reduce regulatory barriers for SMEs, many of which relate to the use of impact assessments (IAs). These initiatives are listed below and explained in more details on this report.

#### **POLICY INITIATIVES TO CUT RED TAPE IN THE SINGLE MARKET**

To reduce unnecessary regulatory burdens through a more systematic, consistent and integrated use of the Better Regulation Toolbox, SMEs call for European policy makers to:

1. Apply the SME Test systematically and consistently early in the IA process
2. Improve the application of the SME Test and the consultation process
3. Ensure clear roles and responsibilities around IAs and SME consultations
4. Include implementation risks in IAs
5. Ensure that IAs are required and conducted for substantial amendments
6. Design and use regulatory sandboxes more actively for SMEs
7. Use the Competitiveness Check as an integrated assessment of impacts on SMEs' global competitiveness
8. Systematically conduct ex-post assessments of SME impacts to ensure institutional memory and evidence-based policy making
9. Explore opportunities for using AI in the regulatory process

# 1 Regulatory barriers erode the competitiveness of European SMEs – why is action needed?

Since its establishment more than 30 years ago, the Single Market has been the engine of EU jobs, growth and prosperity. Its economic size has given the EU political weight in global negotiations and bilateral arrangements. Faced with a more conflictual, volatile and complex world,<sup>3</sup> further reduction of barriers and continued integration are essential for the Single Market to remain the key driver of EU's competitiveness, prosperity and resilience in the future.<sup>4</sup> This has also been explicitly recognised in Mario Draghi's 'The Future of European competitiveness' report from September 2024, which states that 55% of European SMEs consider regulatory obstacles and the administrative burden as their greatest challenge.

In addition, Commission President Ursula von der Leyen has assigned the Implementation and Simplification portfolio to oversee sweeping regulatory simplification measures, including the implementation of dedicated SME and competitiveness checks for all new legislative proposals.

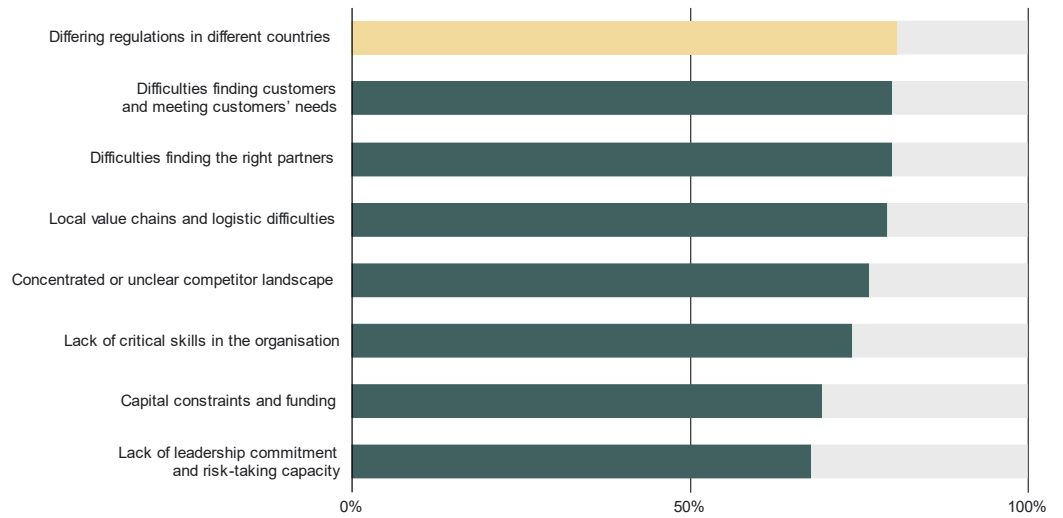
The Single Market has come a long way in removing obstacles to the free flow of goods, services, capital and people across borders. Initiatives to standardise and harmonise regulation across Member States have opened new pathways for growth, particularly for SMEs that have less leverage to allocate resources to map national regulation in potential export destinations, make necessary adjustments and document compliance.

Despite past achievements, the large-scale survey conducted as part of this study clearly demonstrates that **regulatory barriers continue to erode the competitiveness of EU SMEs**, including through lower growth, higher costs and slower digitalisation.

## 1.1 Regulatory barriers hinder growth and increase costs

Differing regulations across Member States (e.g. VAT or differing packing, labelling or recycling requirements) is seen as the most critical barrier for SMEs looking to expand their business through the Single Market. 81% of the SMEs say that differing regulations limits their scope for doing business in the Single Market, see Figure 1.<sup>5</sup>

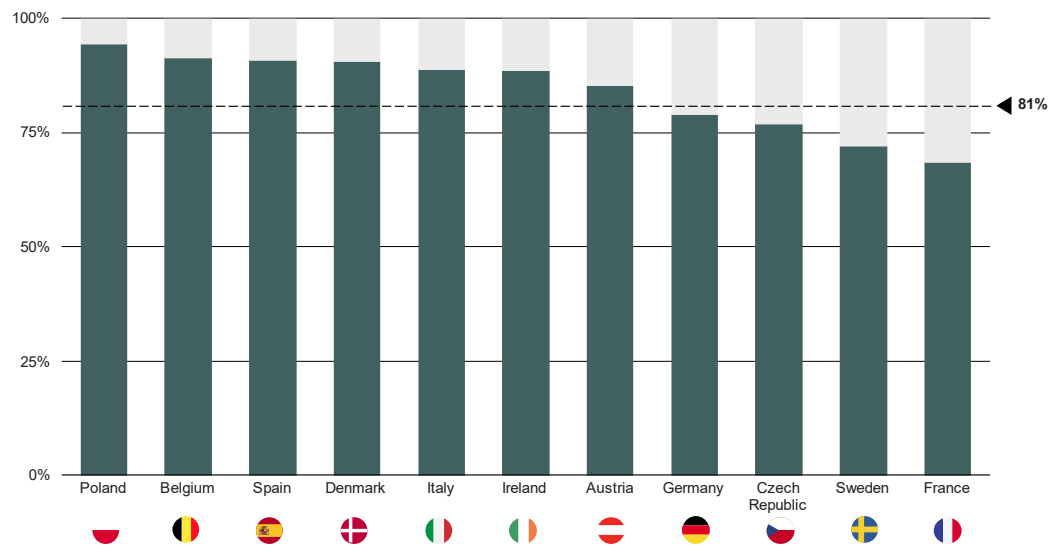
**Figure 1: Differing regulation is the most critical barriers to doing business in the Single Market**



Source: Implement Economics based on a survey of 3,351 EU SMEs in 11 countries.  
 Note: Response to question: 'What do you perceive as the most critical barriers to doing business within the Single Market?', n=2,732. Responses include the answers 'to a lesser extent', 'to some extent' and 'to a great extent'.

Differing regulations is considered a critical barrier by most SMEs across the 11 countries covered by the survey, see Figure 2. In Poland, nearly all SMEs (94%) consider differing regulation as a critical barrier for doing more business in the Single Market, while two-thirds (69%) of the French consider this barrier as critical.

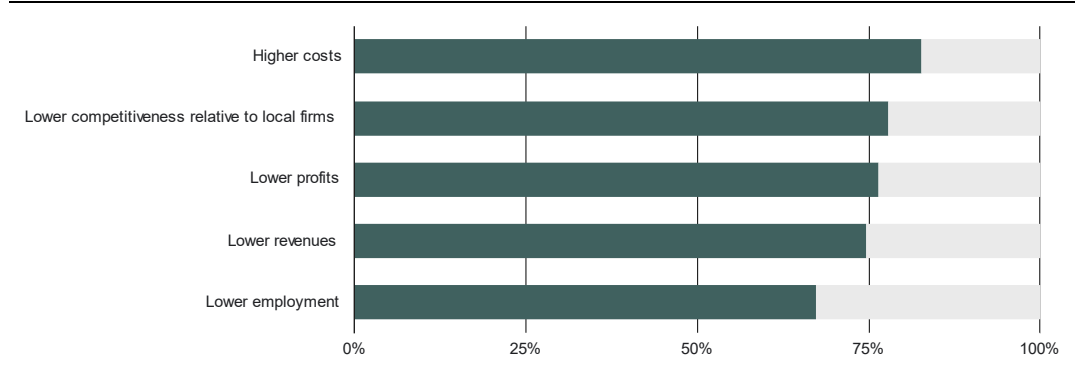
**Figure 2: SMEs almost uniformly identify differing regulations in different countries as a critical barrier**



Source: Implement Economics based on a survey of 3,351 EU SMEs in 11 countries.  
 Note: Response to question: 'What do you perceive as the most critical barriers to doing business within the Single Market? - Differing regulations in different countries (e.g., VAT or differing packaging, labelling, or recycling requirements)', n=2,732. Responses include the answers 'to a lesser extent', 'to some extent' and 'to a great extent'. Average response has been weighted by number of SMEs in each country.

The SMEs report that regulatory barriers increase their costs (83%), erode their competitiveness relative to local firms (78%) and lower their profits (76%), see Figure 3. Because of the regulatory barriers and their consequences for SMEs, members of the Single Market miss out on significant opportunities for creating more benefits for workers through higher job creation, better paid jobs and improved job security. In addition, consumers could benefit from reduced regulatory barriers through lower prices, a wider selection of products, improved product innovation and reduced delivery times.

**Figure 3: Regulatory barriers increase costs and erode the cost competitiveness of SMEs**



Source: Implement Economics based on a survey of 3,351 EU SMEs in 11 countries.

Note: Response to question: 'What are the implications for your business of regulatory barriers to doing business within the Single Market?', n=2,241. Average response has been weighted by number of SMEs in each country. Responses include the answers 'to a lesser extent', 'to some extent' and 'to a great extent'.

The large compliance costs associated with differing regulations are confirmed by stakeholders.

*'The large compliance costs include costs to meet regulatory requirements, expenses related to subcontractors and the duplication of efforts in providing the same information and data across various reports for different institutions. Regulatory charges, especially in the form of taxation, contribute to the overall compliance burden on SMEs.'*

The Association of Small and Medium-sized Enterprises and Crafts of the Czech Republic (AMSP)

## 1.2 Regulatory barriers slow down digitalisation

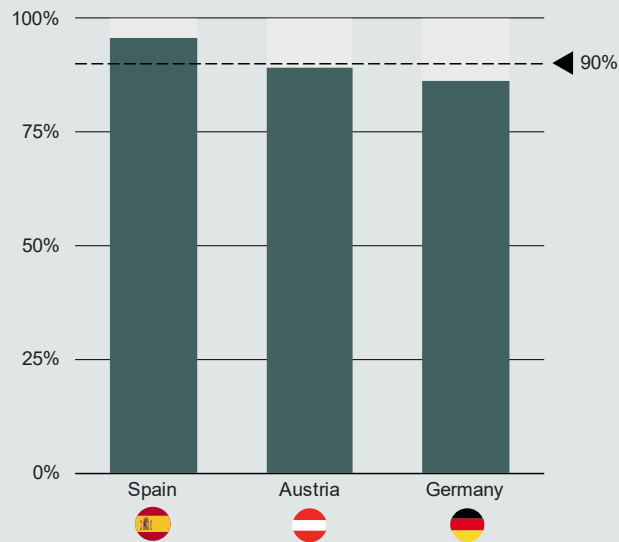
Digitisation is a key driver of productivity, innovation and economic growth.<sup>6</sup> Digital technologies and solutions also enable and accelerate the green transition across the economy and society.<sup>7</sup> Spanish, Austrian and German SMEs confirm that increased digitalisation can help them improve their exports. But they also find that regulatory barriers prevent them from adopting more digital tools, see Box 1. This is confirmed in a survey by the Slovak Alliance for Innovation Economy (SAPIE) from 2023, in which 36% (out of 191) SME respondents and 24% micro-enterprises (out of 326 micro enterprise respondents) highlighted regulations and bureaucracy as one of the key most pressing challenges which prevent them from accelerating the digitalisation of their companies.<sup>8</sup>

### **BOX 1: REGULATORY BARRIERS RISK SLOWING DOWN DIGITALISATION**

Tailored questions from the Spanish, Austrian and German Single Market studies show that on average 90% of the SMEs confirm that increased digitalisation can help them improve their exports. This is particularly the case for Spain, where 96% of the SMEs see an export potential from accelerated digitalisation.



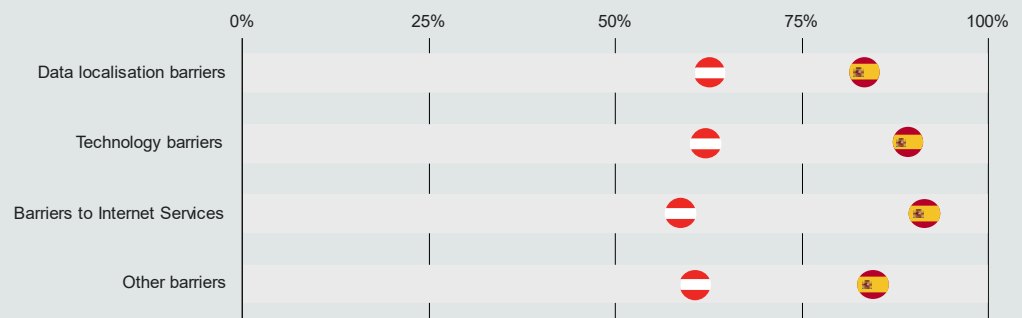
**Figure 4: Increased digitalisation can help SMEs improve their exports**



Source: Implement Economics based on a survey of 1,343 Spanish, Austrian and German SMEs.  
 Note: Response to question: 'To what extent do you think that increased digitalisation / used of digital tools would help your company export more through the Single Market?', n=949. Responses include the answers 'to a lesser extent', 'to some extent' and 'to a great extent'.

Spanish and Austrian SMEs find that certain regulatory barriers prevent them from adopting more digital tools. The most restrictive ones are barriers to Internet Services (including regulatory regimes that limit their use of new business models as well as non-IP-related liabilities), data localisation barriers (including data storage requirements and bans on cross border data flows) and technology barriers (including restrictive security standards and requirements to disclose proprietary source codes).

**Figure 5: Regulatory obstacles hinder SMEs from adopting more digital tools**



Source: Implement Economics based on a survey of 628 Spanish and Austrian SMEs.  
 Note: Response to question: 'To what extent do the following barriers create regulatory obstacles that limit your company's adoption of digital tools?', n=324. Responses include the answers 'to a lesser extent', 'to some extent' and 'to a great extent'.

## 2 Better regulations can reduce regulatory burdens and fragmentation – what should be done?

EU policy makers have repeatedly put forward their commitment to reducing unnecessary regulatory burdens. The guidelines and specific tools in the Better Regulation Toolbox (see Box 2) were updated in 2021 and 2023 with the purpose of adopting high-quality regulation – EU regulations that ‘meet the objective while being targeted, effective, easy to comply with and with the least burden possible’.<sup>9</sup>

### BOX 2: THE BETTER REGULATION TOOLBOX

The Better Regulation Toolbox is a set of tools and methods used by regulatory authorities to improve the quality of regulation and its implementation. The purpose of the toolbox is to ensure that regulations are effective, efficient and proportionate, while minimising unnecessary burdens on businesses and citizens.

The toolbox typically includes a range of instruments such as impact assessments, stakeholder consultations, simplification measures and evaluation mechanisms. These tools help regulators to assess the potential impacts of new regulations, gather input from affected parties, streamline existing rules, and evaluate the effectiveness of regulatory measures.

By using the Better Regulation toolbox, governments and regulatory bodies can promote evidence-based policymaking, enhance transparency and accountability and, ultimately, achieve better outcomes for society as a whole. The toolbox is designed to be adaptable to different policy areas and regulatory contexts, and it provides a systematic approach to improving the quality of regulation while fostering economic growth and innovation.

The SME survey and specific examples brought forward in the stakeholder consultations clearly shows that there continues to be a potential for better regulation to reduce regulatory burdens. The collected responses point to two main areas of improvement. *Firstly*, EU regulations should be designed in a way that makes them **simpler to use and easier to comply with**. EU regulations that cater for the needs of SMEs will reduce compliance costs, strengthen competitiveness and support innovation. *Secondly*, EU regulations should be designed in a way that ensures **even and timely implementation**. Less fragmentation and gold plating enable SMEs to grow through the Single Market.

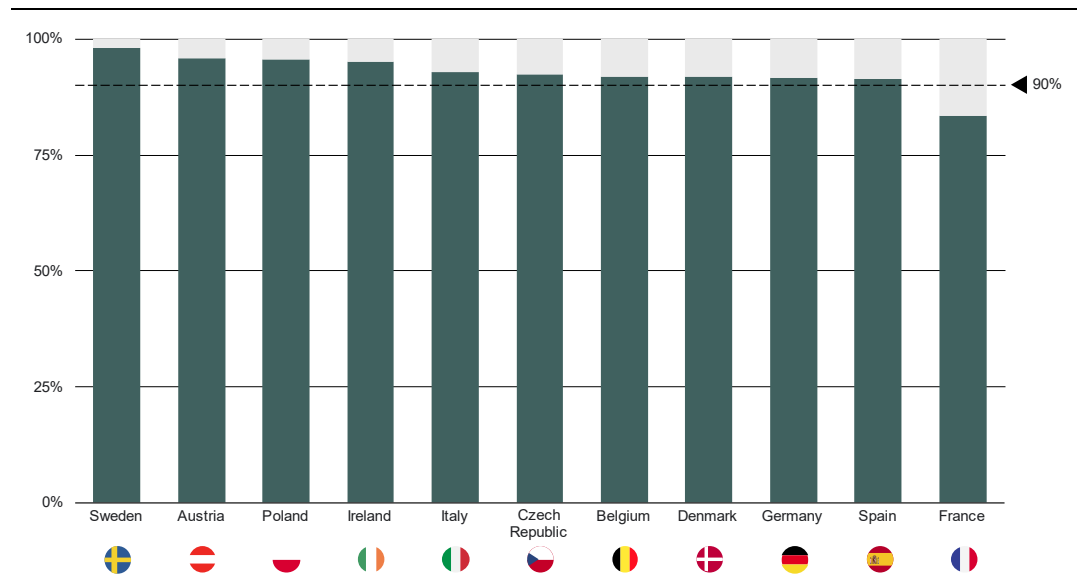
*‘A more consistent application of the impact assessment tools by the European Commission can give insights into EU competitive advantage relative to large and powerful countries such as China and the US. The tool can also raise awareness of new regulatory burdens and possibly reduce gold plating when the EU law is being implemented at the national level.’*

The Impact Assessment Unit at the Business Environment Improvement Department (Slovak Ministry of Economy)

### 2.1 Simpler EU regulations fit for SMEs can reduce compliance costs

The SMEs point to several policy initiatives that can help reduce regulatory barriers.<sup>10</sup> 90% of the SMEs say that simplification of administrative procedures can help them do more business in the Single Market, see Figure 4. The SMEs therefore call for **EU regulations that are simpler and better fit the needs of SMEs**.

**Figure 6: Simplification of administrative procedures can help SMEs grow in the Single Market**



Source: Implement Economics based on a survey of 3,351 EU SMEs in 11 countries.

Note: Response to question: 'To what extent would the following policy initiatives help your company do more business within Single Market? - Simplification of administrative procedures', n=2,385. Average response has been weighted by number of SMEs in each country. Responses include the answers 'to a lesser extent', 'to some extent' and 'to a great extent'.

Commission President von der Leyen announced in 2023 an ambition to reduce reporting obligations for companies by 25%.<sup>11</sup> Nevertheless, the following examples of recently proposed regulations that go in the opposite direction were brought forward in the stakeholder consultations:<sup>12</sup>

- **Corporate Sustainability Due Diligence Directive (CSDDD)** | SMEs will be severely affected by the trickle-down effect of the obligations as many of them are in the value chain of larger companies.<sup>13</sup>
- **Single Market Emergency Instrument (SMEI)** | Monitoring strategic reserves and prioritising orders are obligations that will impact SMEs in European supply chains and risk incurring new regulatory burdens.<sup>14</sup>
- **Forced Labour Product Ban Regulation** | The measures foreseen in the regulation risk hitting SMEs in the supply chain even if they are not responsible or unaware of the use of forced labour.<sup>15</sup>
- **Ecodesign Regulation (ESPR)** | Extending the ESPR will impact SMEs manufacturing these products and those supplying components to bigger manufacturers.<sup>16</sup>
- **Packaging and Packaging Waste Regulation** | New packing requirements with no relief for SMEs will increase costs.<sup>17</sup>
- **AI Act** | The Act will require AI systems to undergo compliance and conformity assessments, which will be associated with high compliance costs for SMEs.<sup>18</sup>

Regarding the necessary strengthening of Europe's competitiveness, stakeholders see a risk that the reporting requirements and compliance costs associated with these initiatives can turn out to be a stumbling block for businesses.

*'Many companies, especially SMEs, are struggling with the increasing cumulative effects of EU legislation. Furthermore, many reporting requirements which are not primarily aimed at SMEs have an impact on them via the supply chain ("trickle-down effect").'*

Austrian Federal Economic Chamber

One example of this is the Carbon Border Adjustment Mechanism (CBAM).

*'The recent entry into force of the CBAM mechanism reveals some critical issues. First, the amount of information to be collected to quantify emissions is significant. For each imported merchandise, SMEs must provide data on the site where the goods were produced, the type of production process used, the sources of emission and the direct and indirect emissions of each production process. Almost all these data must be provided by the producers of the imported goods located in third importing countries, who often prove to be uninformed about the mechanism and unwilling to cooperate. European importing companies are thus exposed to transaction costs and potential risks of sanctions. Secondly, the Commission does not seem to have considered the fact that, if environmental protectionism on raw materials increases, while leaving non-EU finished products free to enter the Community market, this causes damage to the processing sector and accelerates the ongoing process of de-industrialisation.'*

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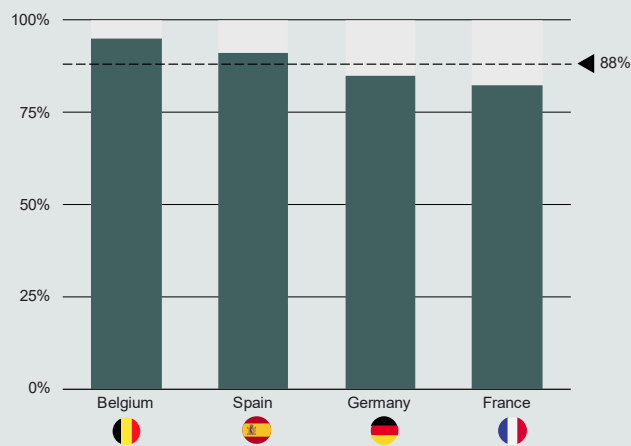
## 2.2 Complete and even implementation reduces fragmentation

Another issue relates to the incomplete implementation of EU rules, gold plating and national layers of regulation that come on top of EU regulation.<sup>19</sup> The Commission estimates that removing existing barriers related to incomplete implementation of EU rules on the Single Market would add an additional EUR 520-600 billion to EU GDP annually (a permanent increase in EU income level).<sup>20</sup> The SMEs confirm that more even and timely implementation of EU regulation will help them export more (see Box 3).

### BOX 3: REGULATORY FRAGMENTATION HINDERS SMEs FROM SCALING UP

Tailored questions from the Belgian, Spanish, German and French Single Market studies show that an average of 88% of the SMEs confirm that more even and timely implementation of EU regulation will help them export more, see Figure 13. This is particularly the case for Belgium, where 95% of the SMEs see an export potential from less fragmented EU regulation.

Figure 7: Even and timely implementation of EU regulation can help SMEs export more

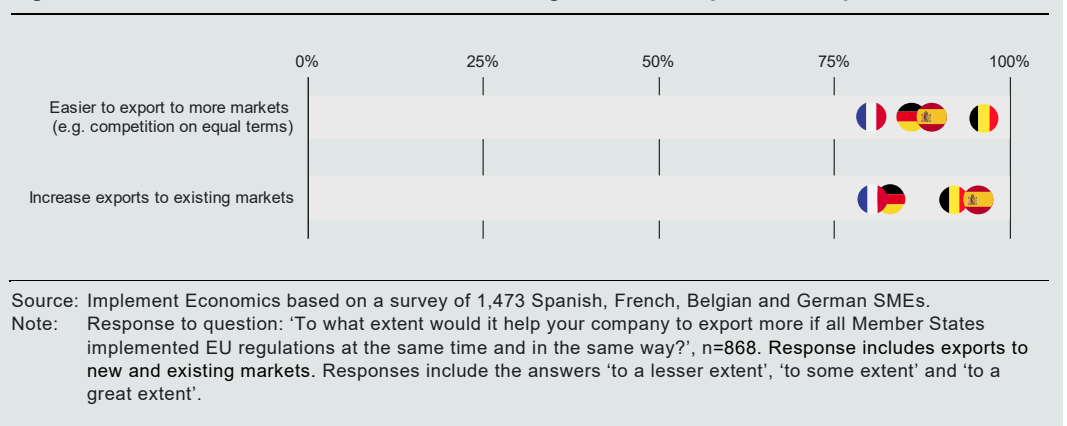


Source: Implement Economics based on a survey of 1,473 Belgian, Spanish, German and French SMEs.

Note: Response to question: 'To what extent would it help your company to export more if all Member States implemented EU regulations at the same time in the same way?', n=868. Responses include the answers 'to a lesser extent', 'to some extent' and 'to a great extent'.

The SMEs generally agree that a national alignment of EU regulation can help them increase exports by either making it easier to export to new markets or by increasing exports to already existing markets, see Figure 18. Notably, almost all surveyed Spanish SMEs (94%) believe that the policy initiatives can help them increase their exports to existing markets.

**Figure 8: Better and more harmonised national EU regulation can help SMEs to export more**



The persistent compliance gap undermines the trust of firms and citizens in the effective functioning of the Single Market. It also sends a clear signal to individual governments that lack of compliance has few consequences – both current and potential new members, in the event of an enlargement. The business cases below demonstrate how regulatory fragmentation currently prevents SMEs from doing more business through the Single Market.

**BUSINESS CASES: REGULATORY FRAGMENTATION CREATES ENTRY BARRIERS**

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Kräutermax is an **Austrian SME** that trades in herbs, natural cosmetics and food supplements. Member States have different interpretations of whether Kräutermax's products classify as food supplements (under EU regulations) or pharmaceuticals (under national regulations). This 'grey area' creates significant uncertainty for the SME and leads to regulatory fragmentation. Limiting these ambiguities is a precondition for ensuring the correct and even application of EU regulations and eventually closing the compliance gap, which is required to lower entry costs and enable SMEs, such as Kräutermax, to expand across the EU.
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General Plastics Scandinavia, based in **Sweden**, trades in a wide range of plastic materials. Many of the materials used by General Plastics Scandinavia are classified as waste and fall under the EU Waste Directive. The firm needs to obtain a statement from the Swedish Environmental Protection Agency that the company complies with EU regulations. This statement is based on the Swedish interpretation of the regulations, which deviate from the German, Austrian, and Italian interpretations. Inconsistent interpretation of common EU regulations and incomplete implementation into national legislation enhance the uncertainty of doing business across borders in the Single Market.
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Inventia Technology is a **Polish company** specialising in the production of natural cosmetics and supplements, including natural collagen. Inventia experiences that different countries interpret and enforce EU regulations relating to nutritional supplements and natural collagen differently, meaning that companies need to navigate variations to ensure compliance in different markets. The differences and 'grey zones' in regulation that exist increase uncertainty. Simplifying and standardising regulations is key to closing the compliance gap, which is needed to lower entry costs and the risks associated with expansion for Inventia.
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BabyFORTE Medical is a **German 20-person company**, specialising in high-quality nutritional supplements for men and women with pregnancy wishes, as well as expectant mothers. Regulatory fragmentation is a considerable challenge for the company and affects a large share of the company's product portfolio. Individual countries within the Single Market have different regulations of BabyFORTE's ingredients, e.g. maximum quantities of micronutrients such as B vitamins, zinc or selenium. There is further variation in whether they classify the product as food supplements or pharmaceuticals. Limiting these ambiguities would increase compliance, while lowering entry costs for BabyFORTE.
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The **French company**, Novoma, produces high-quality food supplements to meet a multitude of different needs for healthy living. Novoma has faced numerous obstacles and delays related to the registration of their food supplements and the preparation of documents necessary for their introduction to a new market (namely Italy, Spain and Germany). This can be even more burdensome in cases where different countries interpret and enforce EU regulations differently – or where additional layers of national regulation exist for food supplements.

While stakeholders also acknowledge the good intentions behind new Commission proposals listed below, they also see them as examples of how new regulations can cause new fragmentations if implementation risks are not foreseen:

- **Critical Raw Materials Act** | As most responsibilities are simply handed to the Member States, no harmonisation of administrative processes has been achieved.<sup>21</sup>
- **Directive on Corporate Sustainability Due Diligence** | Regulatory fragmentation will not be avoided by this proposal as many provisions leave the large discretionary room with the Member States.<sup>22</sup>

## 2.3 Better regulation can reduce burdens

High-quality legislation is a prerequisite for delivering on EU policy objectives in the simplest, most efficient and effective way possible. Moreover, high-quality legislation is a means to avoiding overregulation and unnecessary administrative burdens for citizens, administrations and businesses (particularly SMEs). Finally, high-quality legislation is designed to facilitate its transposition and practical application in the first place.

Removing existing barriers due to the incomplete implementation of EU rules is foreseen to generate large EU-wide economic benefits.<sup>23</sup> The European Commission estimates that removing existing barriers related to incomplete implementation of EU rules on the Single Market would add an additional EUR 520–600 billion to EU GDP annually (a permanent increase in EU income level).<sup>24</sup>

The persistent compliance gap and large administrative costs reported by firms doing business across borders in the Single Market indicate that more can be done to design EU legislation that effectively reduces complexity and administrative costs of doing business in the Single Market. The Better Regulation Toolbox, with impact assessments as a key ingredient, is a way for the Commission to design, deliver and support the implementation of high-quality policies.<sup>25</sup>

The recent high-level report on the future of the Single Market concludes that the main problem identified is lack of impact assessment for legislative proposal or impact assessments of low quality without well measured impacts on SMEs.<sup>26</sup> This recommendation is aligned with the recommendations put forward by the former Prime Minister Enrico Letta in the report *Much more than a market – speed, security, solidarity*. The report was initiated by the Commission to identify initiatives that would empower the Single Market to deliver a sustainable future and prosperity for all EU citizens.

The Letta report contains a dedicated chapter – *A Single Market to go fast and go far* – that emphasises how over-regulation places significant additional costs on businesses, proving unsustainable for SMEs and inadvertently favouring non-European companies that are not bound by the same stringent rules (see Box 4).<sup>27</sup>

Moreover, the report points towards a tendency of 'a risk-averse regulatory approach has led to a surplus of overlapping regulations, creating legal uncertainty and imposing substantial compliance costs' (p. 121). At the same time, so-called "gold plating" exacerbates the challenge, where Member States add additional requirements to EU directives beyond what is stipulated (See Box 4).

#### BOX 4: BETTER REGULATION TO UNLEASH THE POTENTIAL OF THE SINGLE MARKET

The Letta report *Much more than a market – speed, security, solidarity* unequivocally endorses the recommendation to fortify the application of the Better Regulation Toolbox, advocating for its integration at the nascent stages of regulatory design and adherence to impact assessment mandates. It acknowledges the Better Regulation Toolbox as a pivotal element in the EU's regulatory framework, yet it critiques its current iteration for perceived complexity and occasional ambiguity, which could impede stakeholder engagement and obscure the prioritisation of their concerns within Impact Assessments (IAs).

The report underscores the necessity to streamline the Better Regulation Toolbox, suggesting an upgrade without proliferating 'pass or fail' tests and advocating for the inclusion of a robust 'risk-risk assessment' to centralise its application.

Regarding impact assessments, the report identifies a gap between the theoretical framework, which recognises the importance of assessing the impact of co-legislators' amendments, and the practical application, which often falls short. It proposes the introduction of a Dynamic Impact Assessment (DIA) mechanism to provide pragmatic and streamlined updates to the original impact assessments. This would involve 'back of the envelope' evaluations and explicit guesstimates to forecast the implications of amendments, thereby enhancing transparency and informed decision-making.

The report also suggests adopting a 'policy package' approach to facilitate a holistic examination of policies and their impacts, leveraging synergies and minimising unintended consequences. It calls for a systematic consideration of flexibility instruments, such as experimental clauses and regulatory sandboxes, embodying the principles of adaptive regulation.

We recommend the next Commission to strengthen the use of the Better Regulation Toolbox by **upholding the impact assessment requirement, consistently assessing impacts and putting more weight on integrating implementation risks into the design of new regulation.**

The next chapter therefore puts forward specific and actionable initiatives to implement our recommendation to strengthen the use of the Better Regulation Toolbox:

5. Strengthen the use of the Better Regulation Toolbox by integrating implementation into the design of new regulation and consistently respecting impact assessment requirements.

Put more weight on integrating implementation into the design of new regulations and avoid deviations from the requirement to make impact assessments.

## 3 More and better regulation – how to do it?

While SMEs point to significant regulatory barriers in the Single Market, it is often difficult for them to point to specific initiatives that can improve the EU reform process in a way that better caters for their needs. As part of this study, we have therefore consulted stakeholders that in various ways represent SMEs, including business associations, innovation institutions, startup environments and national regulators engaged in Single Market reforms. Stakeholders point to the following nine specific initiatives that could strengthen the use of the Better Regulation Toolbox and reduce regulatory barriers:

1. Apply the SME Test systematically and consistently early in the IA process
2. Improve the application of the SME Test and the consultation process
3. Ensure clear roles and responsibilities around IAs and SME consultations
4. Include implementation risks in IAs
5. Ensure that IAs are required and conducted for substantial amendments
6. Design and use regulatory sandboxes more actively for SMEs
7. Use the Competitiveness Check as an integrated assessment of impacts on SMEs' global competitiveness
8. Systematically conduct ex-post assessments of SME impacts to ensure institutional memory and evidence-based policy making
9. Explore opportunities for using AI in the regulatory process

### 3.1 Apply the SME Test systematically and consistently early in the IA process

The SME Test is a tool designed to assess the impacts of legislative initiatives on SMEs to minimise the burden imposed on them. It consists of four steps, each with its own purpose and set of questions:

**Step 1** | Identification of affected businesses. In this step, the goal is to determine the relevance of the initiative for SMEs.

**Step 2** | Consultation of SME stakeholders. If SMEs are affected by the initiative, it is crucial to include their perspective in the consultation process.

**Step 3** | Assessment of the impact of the initiative on SMEs. The impact assessment report should provide a proportionate assessment of the impacts on SMEs and their ability to grow.

**Step 4** | Minimising negative impacts on SMEs. The impact assessment should consider options that can reduce negative effects and maximise positive impacts on SMEs.

Stakeholders generally find that the four steps can help to minimise the negative impact on SMEs when applied consistently and systematically. However, the SME Test Benchmark 2022 report from BusinessEurope, Eurochambres and SMEUnited concludes that out of 26 impact assessments, only 38% of the reports included one or more sections presenting the SMEs' views.<sup>28</sup>



The business cases below clearly demonstrate that EU regulations currently do not cater for the needs of SMEs and the potential for a more systematic and consistent use of IAs to reduce regulatory burdens for SMEs.

#### **BUSINESS CASES: IMPACT ASSESSMENTS REDUCE THE RISK OF NEW BURDENS**



Nortem BioGroup is a **Spanish SME** that sells natural and ecological food products, cleaning products, cosmetics, and dietary supplements in Spain and across Europe. The company estimates that it takes around 3–12 months to launch in a new country, because it takes time to secure compliance with national and EU regulations. More one-stop shops for information on national requirements and reporting would be a great help. In addition, a more thorough use of the Better Regulation Toolbox would help ensure that EU regulations are designed to fit business needs and cater for SME concerns.



Bosch + Sohn is an **Austrian SME** that specialises in the development and production of medical devices. Costs associated with product approval have at least doubled after the implementation of the new EU Medical Devices Regulation (MDR). Simplifying approval procedures and increasing the number of Notified Bodies would help to ensure that the MDR meets its objectives, namely guaranteeing patient safety and product availability while fostering a sustainable and attractive MedTech innovation landscape in Europe.



Röyk is a **Swedish sustainable clothing brand** that was founded in 2010 after winning an innovation contest. Around 90% of Röyk's production is destined for the Swedish market, but demand for sustainable clothing is increasing across Europe. With the 2018 packaging waste legislation, the company faces new reporting requirements. For a company like them, it is critical that new and ongoing initiatives, such as the new EU Strategy for Sustainable and Circular Textiles and the 2023 revision of the Waste Framework Directive, are coordinated and based on the Better Regulation Toolbox, with solid impact assessments and a focus on implementation.

Stakeholders emphasise that **SME needs should be identified and incorporated into the IA early in the process**. Also, the consultation in step 2 should be carefully planned to ensure that the SMEs understand the complexity and context of the proposal:

*'The four steps in the SME Test may help to minimise the negative impact on SMEs. Before starting the consultation, however, there is a need for assuring a general understanding of the regulations across the different sectors of SMEs. Also, there is a need for increasing awareness on what the potential implications of a new regulations, why it is needed, what it implies for SMEs and how it protects consumers. Only if SMEs understand the context of a particular regulation will the consultation process and assessment be effective.'*

SAPIE

We recommend the Commission to **secure a more consistent and systematic use of the SME Test early in the IA process**. This will reduce the risk of new administrative barriers and unintended negative impacts emerging in the future.

## 3.2 Improve the application of the SME Test and the consultation process

Stakeholders generally find that the application of the SME Test has improved in recent years but also that there is room for further improvement. Stakeholders endorse the implementation of the nine suggestions for improving the SME Test brought forward by the EU Fit for Future Platform, see Box 5.<sup>29</sup>

### BOX 5: SUGGESTED IMPROVEMENTS OF THE SME TEST AND CONSULTATION

The SME Test analyses the possible effects of EU legislative proposals on SMEs. By assessing the costs and benefits of policy options, it helps implement the 'think small first principle' and improve the business environment. The Fit for Future Platform has brought forward the following suggestions: related to the application of the SME Test

1. Introduction of a specific part dedicated to the SME Test
2. Reinforce the analysis of the indirect effect of legislation
3. Analysis of the cumulative impact of legislation
4. Cost calculation using an example company
5. Strengthen the data collection on impacts on SMEs for their timely availability
6. Ensure that periods for public consultation allow sufficient time for reply when they overlap with vacation periods
7. Reinforcement of the role and mandate of the Regulatory Scrutiny Board (RSB)
8. Promote 'ex-post' evaluations of EU law regarding impacts on SMEs
9. Assess significant impacts of implementing acts and delegated acts

Stakeholders put particular emphasis on the first three suggestions from the SME Test Benchmark 2022 report from BusinessEurope, Eurochambres and SMEunited. Firstly, **a specific part dedicated to the SME Test is needed**. Results from a sample of 26 IAs show that only 10 of the IA reports include one or more dedicated sections presenting SMEs' views. Even though public consultations occurred in a majority of examined cases, less than 50% of the examined reports included conclusions from these consultations.<sup>30</sup>

Even when SMEs are exempted from the regulation, their involvement in European supply chains means that they need to comply with EU regulations to be eligible suppliers. In the design of the EU regulations, **both direct and indirect impacts on SMEs should therefore be assessed**. Furthermore, the business cases below clearly show that regulatory requirements cumulate throughout the business journey of European SMEs. As emphasised by the stakeholders, the IA should therefore **consider cumulative impacts of EU legislation**.

*'As other stakeholders, SMEs are not confronted with just one set of (proposed) legislation, but with different more, or less, cohesive sets of legislation. Specific and detailed insights of the cumulative impact of an entire body of legislation on SMEs can reveal risks of incoherence across policy areas, in case different initiatives and policies pursue opposing rather than mutually supporting objectives.'*

Wirtschaftskammer Österreich

### BUSINESS CASES: REGULATORY HURDLES AND INEFFICIENCIES CUMULATE



Café Saula is a specialised **Spanish coffee producer** with a significant presence in Spain. The existing patchwork of directives, regulations and national laws drives up transaction costs. The SME expects its online sales to increase from 10% to 20% if regulatory barriers in the Single Market are removed, which will have positive knock-on impacts on job creation in Spain.



Lough Ree Distillery is a family-owned **Irish distillery business**, specialising in the production of whiskey, gin and vodka. The company exports to over 10 countries within the European Union and finds that doing business in the European Single Market is overall quite seamless. Nonetheless, they face hurdles and inefficiencies along their business journey – e.g. related to the Excise Movement and Control System, as well as the various additional certifications required by some Member States related to the sales and marketing of their alcohol products.



ABS Transportbahnen is an **Austrian SME** that specialises in the manufacturing of inclined lifts and funiculars. In the company's experience EU countries, as well as autonomous provinces, have different legal definitions for lift systems and thus different product and safety requirements. Administrative tasks related to the diverging national and sub-national regulations account for approximately 5–15% of the company's total project costs.

-  Baroni Home is an **Italian e-commerce company**, selling furniture and furnishing accessories both domestically as well as to other countries in Europe. The company has encountered several regulatory obstacles that accumulate over the course of its business journey within the Single Market. The most limiting obstacles for the company relate to taxes and fees, which involve considerable administrative procedures and regulatory uncertainty, and make expansion to other EU countries risky and costly.
-  Fjälkinge Isolering & Plåtservice is a family-owned Swedish company specialising in insulation and sheet metal constructions. The company's services are highly specialised, and the company recruits workers from several EU countries. The construction industry is often regulated by national standards rather than EU legislation, which hinders the reuse of knowledge, materials and tools across countries.
-  Inphysio is a small Polish company specialising in products to support a healthy lifestyle, including products for exercise, massage and recovery. National requirements and various bureaucratic hurdles impede the company's sales on the Single Market, as they need to dedicate time and financial resources to hiring additional consultants to advise on market-specific regulations.
-  Pentagon Sports is a German company selling bicycles, accessories and leisure items over the internet. While Pentagon Sports has experienced growth and success in selling to the European market, expanding to other countries has not been without difficulties and risk. The SME reports that there are simply too many national regulations, laws and requirements for a small company like themselves to keep track of. For example, different countries require different safety logos on the packaging of bicycles and related accessories.
-  Y-Brush is a French manufacturer of y-shaped electric toothbrushes with sonic vibration. Operating in the Single Market, the SME faces significant bureaucratic and regulatory obstacles, particularly concerning the specificity of their product line. National interpretations often differ, introducing uncertainty. For instance, while Y-Brush's toothbrushes are categorised as cosmetic items in Germany, they fall under a distinct category in France, subject to different regulations. Similarly, navigating packaging requirements proves challenging across the European market. To adhere to complex EU and country-specific regulations, Y-Brush must undertake additional measures, thereby escalating operational costs.

### 3.3 Ensure clear roles and responsibilities around IAs and SME consultations

The deficit of high-quality impact assessments indicates a general lack of accountability in the IA and consultation process. In particular, we recommend that the five initiatives described in Box 6 are implemented to **strengthen roles and responsibilities** in the consultation process. Clear roles and responsibilities will be critical to implement the 'ecosystem' approach to IAs initiated by the Commission and included in the Letta report to streamline the Better Regulation Toolbox.

#### **BOX 6: SUGGESTED INITIATIVES TO CREATE CLEARER ROLES AND RESPONSIBILITIES**

The Centre for European Reform lists initiatives to **strengthen roles and responsibilities**:<sup>31</sup>

1. The Regulatory Scrutiny Board should be tasked with 'validating' the Commission's consultation strategies, to help ensure consultation processes are fair, genuine and high-quality.
2. The Commission needs to prepare IAs for all proposals, including for delegated and implementing acts, unless the Commission certifies that the proposal is unlikely to have any significant impacts (after giving stakeholders a chance to challenge that view) or is too urgent (in which case the Commission should clearly justify why it is too urgent to prepare an IA and prepare an IA as soon as possible afterwards).
3. The Commission needs to improve the quality of its IAs, by seeking earlier and more rigorous feedback from stakeholders on draft impact assessments. A 'Competitiveness Check' should be part of IAs - but it should also be integrated into the Commission's political agenda (see detailed description in Section 3.7).

4. The Regulatory Scrutiny Board should become a genuinely independent review body. It should be allocated sufficient resources to review more of the Commission's initiatives.
5. The Council and the Parliament should consult with stakeholders, including consultation by Member States at a domestic level. Both the Council and the Parliament must fulfil their commitment to produce IAs when they put forward substantial amendments to Commission proposals (see detailed description in Section 3.5).

### 3.4 Include implementation risks in IAs

To develop high-quality regulation, the Commission needs to have a thorough understanding of how its proposals should be expected to be implemented at the national level, particularly the risk of regulatory fragmentation. The IA should therefore cover risks of gold-plating, regulatory divergences and other possible implementation issues.

*'Overregulation often translates into additional regulatory burdens, especially for SMEs. It is vital to listen to the national authorities and always integrate perspectives from those who connect with the world of production and businesses. Simple and streamlined procedures are essential for EU competitiveness in an increasingly globalised market.'*

CONFAPI

We propose that the **Commission includes implementation risks in its IAs**. This could be done by collecting data on:

- **Past implementation challenges** | The Commission should examine how similar proposals have been implemented in the past (see also the recommendation on conducting more ex-post IAs in Section 3.8) and what national differences can be observed. Data from the Single Market Scoreboard can be used in the assessment as well as insights systematically collected by the national SOLVIT centres on the application of EU regulations.
- **Future implementation risks** | The Commission should consult with the Member States to understand how its proposals would fit in the national legal orders. Having 'ears on the ground' requires that the Commission can rely on receiving input from a dedicated national Single Market body.

The recommendation to include implementation risks in IAs should therefore be seen in connection with recommendation #2 in the pan-EU Single Market report:

2. Strengthen SOLVIT by establishing a Single Market Ombudsman in every EU Member State and commit SOLVIT to act more proactively on structural cases and to raise awareness.

Designate a Single Market Ombudsman (as head of or in collaboration with SOLVIT) in each Member State as a national, independent body with access to effective remedies. A network of Single Market Ombudsmen is to be set up under the auspices of the European Commission.

### 3.5 Ensure that IAs are conducted for substantial amendments

Stakeholders highlight that even if a Commission proposal is quite proportionate, additional burdens can be added by the co-legislators – the European Parliament (EP) and the Council of the European Union.

*'A better application of the principle of proportionality and a compulsory application of the SME Test and the Competitiveness Check in the IAs can reduce potential regulatory barriers on businesses. However, usually the co-legislators (in particular the EP) often add additional regulatory or administrative burden (e.g. reporting obligations) during the ordinary legislative procedure.'*

Austrian Federal Economic Chamber

According to the Interinstitutional Agreement on Better Lawmaking, the co-legislators should carry out IAs on 'substantive amendments'<sup>32</sup>, but the Agreement leaves quite a margin of discretion for the EP and the Council to decide when and how to conduct an IA. Currently, there are no cases at all where the Council has requested or prepared its own IA for substantial amendments.<sup>33</sup> Stakeholders generally find that co-legislators (the EP and the Council) should carry out IAs.

*'Better law-making contributes to creating a business-friendly environment. Principles of better regulation, including impact assessments and SME tests, should apply in the entire regulatory process. This means that high quality impact assessment should be done to proposals that are subject to substantive amendments in the Council as well as in European Parliament. Next EU institutions should also avoid cumulative burden and be more ambitious when it comes to cutting red tape.'*

Czech Chamber of Commerce

It will be possible to impose some legal obligations on the EP and the Council to conduct IAs for substantial amendments, but only to the extent that those obligations would stem from the EU Treaties such as the proportionality principle (which is legally binding for the co-legislators). Beyond those limited obligations, the solution to the lack of IAs would be more of a political nature, e.g. for the Commission to threaten to withdraw proposals if it is subject to substantial amendments that are not motivated and/or the conduct of an IA on such amendments by an independent organ (such as the Commission) with the hope that it will mitigate the risk of 'rogue' amendments in the legislative process (i.e. relying instead on transparency and/or 'name and shame' approach). This recommendation can therefore be implemented by:

- Committing the Commission to 1) conduct an IA of the most substantial amendments proposed by the EP and the Council or 2) withdraw any of its proposal if the EP and/or Council do not provide an IA for the most substantial amendments.
- Adopting an EU legal act that would oblige the EU institutions (incl. the EP and the Council) to demonstrate that any proposed amendment complies with certain of their Treaty-based obligations (e.g. the principles of subsidiarity and proportionality).
- Making certain parts of the IA legally binding (incl. the SME Test) and securing a right to challenge proposals that contradict these principles.

### 3.6 Design and use regulatory sandboxes more actively for SMEs

The OECD defines regulatory sandboxes as a 'regulatory safe space for businesses, enabling them to test innovations with reduced regulatory requirements. As relaxing regulatory requirements can potentially raise additional risks, most regulatory sandboxes operate in a controlled environment which includes several safeguards. After a defined period, innovators may apply for an authorisation outside the regulatory sandbox'.<sup>34</sup>

Sandboxes can 'allow SMEs to test out new services, technology, apps, innovative ideas, in a controlled regulatory space, while at the same time enable regulators to provide them with regulatory guidance and to test how the regulation is complied with and whether adjustments are needed for SMEs in particular. This can have the advantage of not creating large costs for SMEs of figuring out the regulatory environment as they begin to operate in a new (potentially risky) market and allow regulators to understand the market to better regulate it'.<sup>35</sup>

As highlighted in the Letta report, regulatory sandboxes can also help regulators understand the implications of new technologies and business models, identify potential regulatory barriers, and develop more agile and responsive regulatory frameworks. By providing a safe space for testing and learning, regulatory sandboxes can help accelerate

the pace of innovation while maintaining appropriate regulatory oversight, e.g. to ensure that SMEs do not risk falling out of EU value chains due to unintended consequences of EU regulations.

Stakeholders emphasise that regulatory sandboxes can **reduce regulatory burdens**:

*'Effective cooperation through regulatory sandboxes can reduce regulatory burdens for SMEs and enable the effective implementation of necessary regulatory requirements into a company's day-to-day operations. By providing a space for SMEs to experiment with new ideas while still adhering to regulatory standards, sandboxes promote innovation and entrepreneurship by mitigating the risks associated with regulatory compliance, ultimately supporting the development and expansion of small businesses.'*

Crowdberry (the leading Slovak investment platform)

Stakeholders also confirm that regulatory sandboxes can **stimulate innovation and competitiveness**:

*'Regulatory sandboxes are an important tool to give SMEs the space, they need to try out innovations on a day-to-day basis. This enables innovations to reach market maturity more quickly and, thereby, strengthen long-term EU competitiveness.'*

Austrian Federal Ministry of Labour and Economy

Finally, stakeholders argue that regulatory sandboxes can **accelerate the internationalisation of EU SMEs**:

*'Regulatory sandboxes are a promising tool to empower innovation and competitiveness in regulated industries. A pan-European sandbox might also allow startups to think European from day one instead of staying in their local markets for the first few years.'*

AustrianStartups

The Better Regulation Toolbox (tool #69 on emerging methods and policy instruments) provides guidelines on which element to consider before setting up a regulatory sandbox. Stakeholders encourage law makers to **use regulatory sandboxes more actively and explore how these sandboxes can be designed and implemented in a way that reduces regulatory burdens for SMEs when proposing new EU regulations**.

### 3.7 Use the Competitiveness Check as an integrated assessment of impacts on SMEs' global competitiveness

SMEs form the backbone of the EU economy, accounting for 96% of all EU firms and 52% of GDP in the EU.<sup>36</sup> Likewise, SMEs account for 64% of EU private sector employment<sup>37</sup> and are key drivers of innovation, as they bring innovative solutions to global challenges like climate change.<sup>38</sup> It is within this group of companies that the next EU unicorn is likely to be found. Despite their large number, SMEs accounted only for 37% of total EU exports in 2021, reflecting that exporting exposes SMEs to numerous barriers (including regulatory and administrative ones) and is a difficult activity that requires significant financial and human resources. Preserving and strengthening SMEs' global competitiveness is therefore of utmost importance.

A new annex in the Better Regulation Toolbox from July 2023 includes a Competitiveness Check, which aims to evaluate impacts of regulatory changes on SMEs' competitiveness across four competitive dimensions:

- **Cost and price competitiveness** | Examination of the impact of an initiative on the cost and price competitiveness of goods and services. Factors considered include the cost and availability of production factors, and compliance costs for companies.

- **International competitiveness** | Impact of an initiative on the competitive position of EU firms compared to non-EU competitors. This includes assessing changes in trade and trade barriers, and adherence to international standards and regulatory approaches.
- **Capacity to innovate** | Evaluation of the impact of an initiative on the capacity of enterprises to innovate. It considers factors such as R&D capabilities, and intellectual property rights protection.
- **SME competitiveness** | Examination of whether the direct impact on SMEs differs significantly from that on large companies, and the potential indirect effects on SMEs through the value chain or subcontracting.

Stakeholders generally find that the four steps can help to minimise the negative impact on SMEs when **applied consistently and systematically**, but it remains to be seen whether and how the Competitiveness Check is implemented in reality. The RSB has been tasked<sup>39</sup> to also focus on the correct application of the new Competitiveness Check, and the RSB will report<sup>40</sup> on its first experience on the Competitiveness Check in next year's annual report. Stakeholders particularly see a need to apply the Competitiveness Check in the regulatory push for a more sustainable economy:

*'Given EU ambitions to achieve full energy autonomy, accelerate the green transition and enhance environmental sustainability, the dimensions of the Competitiveness Check should be integrated in a consolidated assessment of impacts on SME competitiveness, also emphasising green competitiveness and environmental sustainability.'*

CONFAPI

and

*'To maintain and ideally to even increase the competitiveness of EU enterprises, including SMEs, EU policy makers should ensure that new regulations do not significantly impact their competitiveness on the world market. For instance, excessively strict environmental standards of the EU, which are unparalleled in the world, can put EU enterprises at a disadvantage compared to their US or Chinese rivals. Hence, the Competitiveness Check be integrated with the SME Test.'*

Slovak Business Agency and Comenius University in Bratislava

Finally, stakeholders encourage the Commission to take an **integrated approach** to implementing the Competitiveness Check:

*'It is not enough to treat the Competitiveness Check as one of many topics in the general IA process. There needs to be a real focus on competitiveness. Special efforts should be made to ensure that this instrument will present and review in an integrated manner the expected impact of the individual proposals on competitiveness at cost and price level, international competitiveness and innovative capacity, as well as on the competitiveness of SMEs.'*

Austrian Federal Ministry of Labour and Economy

Furthermore, stakeholder argue that the following initiatives can improve the Competitiveness Check:

- Ensure systematic and uniform application of the Competitiveness Check throughout the legislative process.
- Involve affected businesses through targeted consultations to gather feedback on the impact of proposed regulations.
- Consider integrating a category of green competitiveness and environmental sustainability within the Competitiveness Check.
- Focus on the competitiveness in terms of attracting international talent.
- Ensure that the Competitiveness Check is conducted with a specific and detailed insight of the cumulative impact of an entire body of legislation on SMEs.

### 3.8 Systematically conduct ex-post assessments of SME impacts to ensure institutional memory and evidence-based policy making

Stakeholders call for EU law making to be more evidence-based and relying on data of higher quality:

*'Careful assessment of the impacts of EC proposals on SMEs can help to avoid negative impact on entrepreneurs. The SME Test must be applied regularly, this in more systematic and proportionate manner.'*

Czech Chamber of Commerce

and

*'A fundamental reorientation on the quality of the regulatory framework is needed to avoid excessive burdens for businesses from the outset. The reliability of any analysis is proportional to the information available. Partial or missing data put the validity of the analyses at risk. While it is understandable that quality data is not always available, the utmost should be done to further collect relevant and usable information.'*

Austrian Federal Economic Chamber

To both ensure institutional memory and close potential information gaps, we recommend the Commission to **systematically conduct ex-post assessments of SME impacts**. Ex-post evaluations can be used to assess whether a specific intervention was justified and whether it worked (or is working) as expected in achieving its objectives and why. Ex-post evaluations should also look for unintended effects (i.e. those which were not anticipated at the time of the IA) and look for evidence of causality.

### 3.9 Explore opportunities for using AI in the regulatory process

Recent studies suggest that AI can help governments become more efficient in making regulations by supporting the process of developing, commenting on, reviewing and publishing regulations.<sup>41</sup> We recommend the Commission to **gather learnings** (costs, benefits and risks) from existing use of AI in the regulatory process at the national level and **run pilot tests** of the most promising application areas at the EU level. Opportunities to be explored should as a minimum include:

- **Managing inputs from stakeholders** | Reviewing, consolidating and analysing inputs from stakeholders can be a resource-demanding challenge. In consultation processes with massive volumes of comments, AI can enhance efficiency and speed.
- **Reduce complexity of rulemaking** | Text analytics that tag data for meaning can produce machine-readable text that can allow policy makers to identify parts of new rulemaking needing coordination, offer retrospective review of prior rules and map opportunities to reduce duplication in multiple rulemakings. Machine readable text can also help the public identify parts of a regulation of particular interest to them, helping them to provide meaningful comments.



## Appendix

The questionnaire distributed to the stakeholders contains 19 questions related to:

- The Better Regulation Toolbox (question 1-7)
- The SME Test (question 8-12)
- The Competitiveness Check (question 13-16)
- Regulations under negotiation (question 17-19)

### Questions related to the Better Regulation Toolbox

The Better Regulation Toolbox is designed to support the European Commission's commitment to making EU law simpler and less costly. It provides practical advice and methodological guidance for all those involved in preparing, implementing and evaluating EU policies. The toolbox contains 69 tools to follow when preparing a legislative proposal. Please share your perspectives on the following questions.

1. Can the application and implementation of the Better Regulation Toolbox be improved? If yes, please elaborate.
2. What parts of the Better Regulation Toolbox are particularly beneficial for SMEs, entrepreneurs and larger companies?
3. Can a strengthening of the Better Regulation Toolbox reduce regulatory barriers for SMEs, entrepreneurs and larger companies? If yes, please elaborate.
4. Can a more consistent application of impact assessments by the European Commission reduce regulatory burdens from new EU regulation? If yes, please elaborate.
5. Can new tools be added to the Better Regulation Toolbox to the benefit of SMEs, entrepreneurs and larger companies? If yes, please elaborate.
6. Can regulatory sandboxes reduce regulatory burdens for SMEs if included in the Better Regulation Toolbox? If yes, please elaborate.
7. Do you have other comments related to the Better Regulation Toolbox? If yes, please elaborate.

### Questions related to the SME Test

The SME Test is a tool designed to assess the impacts of legislative initiatives on SMEs to minimise the burden imposed on them. It consists of four steps, each with its own purpose and set of questions:

**Step 1 |** Identification of affected businesses. In this step, the goal is to determine the relevance of the initiative for SMEs.

**Step 2 |** Consultation of SME stakeholders. If SMEs are affected by the initiative, it is crucial to include their perspective in the consultation process.

**Step 3 |** Assessment of the impact of the initiative on SMEs. The impact assessment report should provide a proportionate assessment of the impacts on SMEs and their ability to grow.

**Step 4 |** Minimising negative impacts on SMEs. The impact assessment should consider options that can reduce negative effects and maximise positive impacts on SMEs.

8. Can the four steps in the SME Test be improved? If yes, please elaborate.
9. Can the application, implementation and timing of the SME Test be improved? If yes, please elaborate.

10. Are sufficient mitigation actions generally taken? If yes, please elaborate.
11. Can the consultations with SMEs and other stakeholders be improved? If yes, please elaborate.
12. Do you have other comments related to the SME Test? If yes, please elaborate.

### Questions related to the Competitiveness Check

The Better Regulation Toolbox includes a Competitiveness Check, which evaluates the regulatory changes on SMEs' competitiveness across four competitive dimensions:

- **Cost and price competitiveness** | Examination of the impact of an initiative on the cost and price competitiveness of goods and services. Factors considered include the cost and availability of production factors, and compliance costs for companies.
  - **International competitiveness** | Impact of an initiative on the competitive position of EU firms compared to non-EU competitors. This includes assessing changes in trade and trade barriers, and adherence to international standards and regulatory approaches.
  - **Capacity to innovate** | Evaluation of the impact of an initiative on the capacity of enterprises to innovate. It considers factors such as R&D capabilities, and intellectual property rights protection.
  - **SME competitiveness** | Examination of whether the direct impact on SMEs differs significantly from that on large companies, and the potential indirect effects on SMEs through the value chain or subcontracting.
13. Are the four dimensions in the Competitiveness Check relevant and sufficient? Please elaborate.
  14. Are the four dimensions equally important? Please elaborate.
  15. Can the application, implementation and timing of the Competitiveness Check be improved? If yes, please elaborate.
  16. Do you have other comments related to the Competitiveness Check? If yes, please elaborate.

### Questions related to regulation under negotiation:

17. Are there any proposed regulations that risk for imposing new regulatory burdens on SMEs? If yes, please elaborate.
18. Are there newly adopted regulations where you think that the underlying impact assessment from a SME perspective was conducted with high quality? With poor quality? Please elaborate.
19. Are you aware of SMEs that would be willing to participate in an interview around their experience with handling regulatory barriers?

## List of endnotes

- <sup>1</sup> Implement Consulting Group (2024). *A path to prosperity, competitiveness and growth: putting SMEs back at the centre of the Single Market*. The report can be downloaded at <https://implementconsultinggroup.com/article/a-reboot-of-the-single-market>.
- <sup>2</sup> European Commission (2023). *Enrico Letta on the Future of the Single Market*. European Commission press release 15 September 2023.
- <sup>3</sup> European Commission (2023). *Enrico Letta on the Future of the Single Market*. European Commission press release 15 September 2023.
- <sup>4</sup> European Commission (2023). *EU competitiveness beyond 2030: looking ahead at the occasion of the 30th anniversary of the Single Market*.
- <sup>5</sup> Implement Consulting Group (2024). *A path to prosperity, competitiveness and growth: putting SMEs back at the centre of the Single Market*.
- <sup>6</sup> European Commission (2020). *Shaping the digital transformation in Europe*.
- <sup>7</sup> Implement Consulting Group (2022). *Digital Decarbonisation - How the Digital Sector is Supporting Climate Action*, commissioned by Google.
- <sup>8</sup> Interview with Michal Kardoš from SAPIE.
- <sup>9</sup> European Commission (2021). *Better Regulation Guidelines*. Commission Staff Working Document SWD(2021) 305 final.
- <sup>10</sup> The response categories used in this survey questions are based on the business survey from Eurochambres (2020). *The State of the Single Market: Barriers and Solutions*.
- <sup>11</sup> European Commission (2023). *Long-term competitiveness of the EU: looking beyond 2030*.
- <sup>12</sup> Many of these examples are explained in more detail in the feedback from the Austrian Federal Economic Chamber at [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13990-Administrative-burden-rationalisation-of-reporting-requirements/F3444917\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13990-Administrative-burden-rationalisation-of-reporting-requirements/F3444917_en).
- <sup>13</sup> See <https://www.smeunited.eu/news/smeunited-published-its-position-paper-on-the-directive-on-corporate-sustainability-due-diligence-csddd>.
- <sup>14</sup> See <https://www.smeunited.eu/news/smei-smes-cant-be-neglected-they-are-a-fundamental-part-of-our-society>.
- <sup>15</sup> See <https://www.smeunited.eu/news/proposal-to-ban-forced-labour-products-lacks-clear-priorities>.
- <sup>16</sup> See <https://www.smeunited.eu/news/take-a-step-by-step-approach-to-ecodesign-product-priorities>.
- <sup>17</sup> See <https://www.smeunited.eu/news/revised-packaging-rules-put-additional-constraint-on-smes>. See proposal for a regulation.
- <sup>18</sup> See <https://www.digitalsme.eu/the-ai-act-help-or-hindrance-for-smes/>.
- <sup>19</sup> European Parliamentary Research Service (2014). *The Cost of Non-Europe in the Single Market*.
- <sup>20</sup> European Commission (2020). *A Single Market that Delivers for Businesses and Consumers*.
- <sup>21</sup> See <https://www.smeunited.eu/news/smeuniteds-assessment-of-the-critical-raw-materials-act>.
- <sup>22</sup> See <https://www.smeunited.eu/news/smeunited-published-its-position-paper-on-the-directive-on-corporate-sustainability-due-diligence-csddd>.
- <sup>23</sup> European Parliamentary Research Service (2014). *The Cost of Non-Europe in the Single Market*.
- <sup>24</sup> European Commission (2020). *A Single Market that Delivers for Businesses and Consumers*.
- <sup>25</sup> European Commission (2021). *Better Regulation' Toolbox 2021* (Ch.1).
- <sup>26</sup> High Level Report on the future of the Single Market (2024). *Input on SMEs and better regulation*.
- <sup>27</sup> Non-paper of Croatia, Czechia, Denmark, Estonia, Finland, Ireland, Latvia, Lithuania, Malta, The Netherlands, Poland, Portugal, Slovakia, Slovenia and Sweden on a new horizontal Single Market Strategy.
- <sup>28</sup> The full report can be found at [https://commission.europa.eu/system/files/2023-11/final\\_opinion\\_2023\\_1\\_sme\\_test.pdf](https://commission.europa.eu/system/files/2023-11/final_opinion_2023_1_sme_test.pdf).
- <sup>29</sup> The nine suggestions were presented by SMEunited Secretary General Véronique Willems and Dutch SME Envoy Pieter Waasdrop in November 2023. The full report can be found at [https://commission.europa.eu/system/files/2023-11/final\\_opinion\\_2023\\_1\\_sme\\_test.pdf](https://commission.europa.eu/system/files/2023-11/final_opinion_2023_1_sme_test.pdf).
- <sup>30</sup> Business Europe, Eurochambres and SMEunited (2022). *SME test benchmark 2022 – making better regulation work better for SMEs*. The full report can be found at <https://www.eurochambres.eu/publication/sme-test-benchmark/>.

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- <sup>31</sup> Centre for European Reform (2024). *Better Regulation in Europe: An Action Plan for the Next Commission*.
- <sup>32</sup> Official Journal of the European Union. *Interinstitutional agreement between the European Parliament, the Council of the European Union and the European Commission on better law-making* (April 2016).
- <sup>33</sup> Presidency/General Secretariat (2023). *Impact assessment within the Council - 2023 annual report*. June 16th 2023, paragraphs 30 and 32.
- <sup>34</sup> See OECD Regulatory Policy Outlook 2021.
- <sup>35</sup> See OECD (2022). *The SME Test: Taking SMEs and entrepreneurs into account when regulating* (Chapter 6).
- <sup>36</sup> Eurostat (2023). *Annual enterprise statistics by size class for special aggregates of activities (NACE Rev.2) [SBS\_SC\_SCA\_R2]*.
- <sup>37</sup> Eurostat (2023). *Persons employed in the non-financial business economy by size class of employment [TIN00148]*.
- <sup>38</sup> European Commission (2022). *Internal Market, Industry, Entrepreneurship and SMEs*.
- <sup>39</sup> See European Commission (2022). *Decision of the President of the Commission amending Decision P(2020)2 as regards the composition of the Regulatory Scrutiny Board, the quorum for its decisions and the focus of its tasks*.
- <sup>40</sup> See Regulatory Scrutiny Board (2022). *Annual Report 2022*.
- <sup>41</sup> See, for example, D. Chenok and V. Huth (2023). *How can AI improve the regulatory process?*.

