

SME TEST BENCHMARK 2024



**MAKING BETTER
REGULATION
WORK BETTER
FOR SMES**

FOREWORD

As highlighted in European Commission President von der Leyen's political guidelines, small and medium-sized enterprises (SMEs) are essential to Europe's prosperity and competitiveness. However, despite their contribution to job creation and wealth generation, SMEs still encounter considerable challenges. Key among these is a complex regulatory environment, which has intensified over the past number of years.

While better regulation for SMEs has been growing in relevance on the EU agenda, along with ambitious announcements and new tools proposed, the correct and consistent application of the SME Test remains a milestone of the EU legislative process. The SME Test is a key tool for achieving policy objectives in a manner that avoids unnecessary and disproportionate burdens, building on the rationale of the "Think Small First" principle.

This analysis has a renewed importance in light of the proposal on Dynamic Impact Assessments in the report on the future of the Single Market by Enrico Letta, and the conclusions of the report on the future of European competitiveness by Mario Draghi. The latter stresses that, while about 80% of the European Commission Work Programme items are relevant to SMEs, only around half of impact assessments substantially focused on these companies.

Following our first joint report in 2022, BusinessEurope, Eurochambres, and SMEunited have joined forces again to assess the application of the SME Test across European Commission services on legislative proposals published in the second half of the EU cycle 2019-2024.

We are proud to submit our second joint report and our recommendations for better SME policymaking for consideration by the European Commission, other EU institutions, and the broader SME policy community.



A blue ink signature of Markus J. Beyrer, written in a cursive style.

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1 EXECUTIVE SUMMARY

The reduction of regulatory and administrative burden for businesses and the better law-making process, for SMEs in particular, remain high on the European Commission's political agenda for the new legislative term. Nevertheless, better regulation tools already exist and were further expanded with the introduction of new SME-dedicated tools, such as the SME Filter, and actions announced under the 2023 SME Relief Package.

On top of all these initiatives, the SME Test remains a key element of the law-making process as it seeks to identify potentially negative impacts of new legislation on SMEs and propose offsetting measures to minimise them. However, good intentions must be backed by a stronger political commitment: in practice, better law-making is still not considered a collective responsibility of all European Commission's Directorates-General and all EU Institutions.

This year's report intends to factor in the new elements introduced in the preparatory work for a legislative proposal and assess, once again, the extent to which the European Commission actually considers the impact on SMEs and the risk of potential additional burdens.

For this reason, 23 impact assessments (IAs) were analysed on the basis of the better regulation guidelines (2021) and toolbox (2023) by the European Commission. Based on these findings, the report provides recommendations for better policy-making for SMEs. Similarly to our 2022 analysis, this new report concludes that the SME Test is still not systematically and consistently applied across the European Commission's services.

On a positive note, our 2024 analysis shows that almost every IA considers whether SMEs are affected by the proposal, even though this was the case only for fewer Calls for evidence (CfE) or Inception Impact Assessment (IIA). A vast majority of consultations were held in all EU official languages and allowed respondents to identify themselves as SMEs or SME representatives. Furthermore, other consultation methods were often employed, and SMEs' views were generally fairly represented.

Other areas that are in need of improvement include respecting the 12-week consultation period and granular presentation of the information gathered during the consultations. The presentation of the impact of proposals on SMEs is not always clear, with 7 out of 23 legislative initiatives lacking a dedicated SME Test chapter.

Several sections of this report provide comparisons between the 2022 and 2024 editions of the report. The main findings of this year's report are listed in the section below. Based on this, policy recommendations are presented in Chapter 5.

MAIN FINDINGS

The report identified the following main findings as overall positive:

- 22 out of 23 impact assessments (IA) consider whether SMEs are affected by the proposal. However, only 15 out of 23 Calls for evidence (CfE) or Inception Impact Assessment (IIA) assess whether SMEs are affected by the proposal.
- 20 out of the 23 consultation questionnaires allowed the respondents to identify themselves as individual SMEs (by size) or SME representatives.
- 20 out of 23 consultations included a questionnaire in all EU 24 official languages (or 23 excluding Irish).
- In 20 out of 23 consultations, the Commission services employed other consultation methods, such as SME panels.
- 18 out of 23 IAs present the views of SMEs either in a dedicated section as part of the SME Test, or throughout the IA report, together with the views of other stakeholders.

The report identified the following main findings as points for improvement:

- Out of the 23 legislative initiatives, only 17 respected the 12-week period for consultation. In addition to this, more than half of the consultations (12 out of 23) overlapped with holiday periods, although 9 of them were extended to ensure greater participation in the consultative process.
- While 20 out of 23 IAs used the information collected during the consultation, the clarity and details of the information reported vary greatly among the 20 IAs.
- While 22 out of 23 IAs referred to differences between the impacts of legislative initiatives on SMEs and on large companies, subdivision between various groups of SMEs – micro, small and medium sized companies – is only partly made in 4 out of the 23 IAs.
- The presentation of the impact on SMEs is not always clear, and 7 out of 23 legislative initiatives lack a dedicated SME Test chapter which would support a clear and comprehensive presentation of the results.
- Quantitative analysis of the impact on SMEs was carried out for 13 out of 23 IAs.
- The impact on SMEs was measured for all policy options in 19 out of 23 initiatives. However, there remain significant differences between the assessments, most of them being qualitative, not quantitative.

2 RATIONALE

While it is crucial to be attentive to developments after the publication of an EU proposal, such as the introduction of direct or indirect costs on SMEs, the correct application of the SME Test remains a key pillar to deliver proportional legislative proposals. For this reason, this report focuses exclusively on the SME Test application, building on the recommendations the three organisations made in 2022.

The analysis in this report is carried out on 23 IAs of legislative initiatives of relevance to SMEs across a total of 11 directorates general (DGs). This confirms the nature of the exposure of SMEs to several policy areas. Further information on the breakdown of DGs is available in Annex 1.

To ensure consistency with the work of the European Commission, the three organisations focused only on initiatives relevant to SMEs and that were supported by an IA. However, several initiatives – relevant to SMEs according to the three organisations – did not foresee an IA or in some cases, not even an open public consultation. In such cases, the European Commission proceeded by publishing a Staff Working Document (SWD) – usually a few weeks or months after the proposal’s publication – with estimates on the expected impact. Such estimates are, however, not based on the results of an open public consultation. A few examples are the Regulation of forced labour¹, the European Chips Act², the Net Zero Industry Act³, the Regulation on the EU Electricity Market design⁴, with the latter also included in the SME Filter process and considered as relevant for SMEs.

Following our analysis published in 2022 covering the first part of the EU institutional cycle (2019-2022), this edition’s analysis covers the second half of the past EU institutional cycle (2022-2024), with one exception in 2021. The IAs were analysed against the European Commission’s 2021 better regulation guidelines and 2023 toolbox, following the four steps of the SME Test:

1. Identification of affected businesses,
2. Consultation of SME stakeholders,
3. Assessment of the impact on SMEs,
4. Minimising negative impacts on SMEs.

In relation to these steps, this exercise investigates how early in the process the needs of SMEs were considered and how precisely assessed, whether public consultations were correctly held and the SME views adequately presented in the IAs reports. It also investigates whether other consultation methods were employed and how the consultation results were factored in the policy options proposed. A particular attention was paid to the assessment of the impact on SMEs and the policy options proposed.

Lastly, the report identifies whether and under which circumstances mitigating measures were proposed.

¹ Based on a targeted consultation, no IA foreseen but only a SWD.

² According to the proposal: “Given the urgent need to act, no impact assessment was carried out and no online public consultation was foreseen”

³ According to the proposal: “Given the urgent need to act, no impact assessment was carried out and no online public consultation was foreseen. The analysis and all supporting evidence will be set out in a staff working document published at the latest within three months of the proposal’s publication.”

⁴ According to the proposal: “Given the urgency of the initiative, a SWD has been produced instead of an impact assessment.”

Steps 2 and 3 were each assigned a score between zero and five, for a maximum of ten points in total. To better reflect the latest set of better regulation guidelines, the three organisations agreed on a revised methodology. The new methodology was presented and discussed with the European Commission.

Given the sample of IAs analysed, the three organisations aimed to identify the main trends and differences compared to the 2022 report. As a novelty, this report features two new sections on the role of the SME Filter and on the Regulatory Scrutiny Board opinions.

BusinessEurope, Eurochambres, and SMEUnited consider the results presented hereafter as an extremely relevant source of information for improving the formulation process of new initiatives.

After presenting the main results of our analysis in Chapter 4, a set of recommendations based on the four steps of the SME Test is provided in Chapter 5. These serve as a call for immediate action for the new European Commission in ensuring a more coherent and consistent application of the SME Test among its services as a key contributor tool to the European better regulation agenda.

3 OVERVIEW OF ASSESSED FILES

Name of proposal	Acronym used in the report	IA report reference	Date of the IA	DG(s)	Relevance to SMEs
Communication on EU Climate target for 2040	EU Climate target 2040	SWD(2024) 63 final	06.02.2024	DG CLIMA	All segments of the EU economy are and will be affected by climate change, although some sectors are more exposed than others, notably agriculture, tourism, fisheries, and forestry. SMEs have a more limited financial capacity and lower resources to adapt to climate change. To contribute to limiting climate change globally through the implementation of the objective of climate neutrality by 2050, this initiative aims at assessing a 2040 EU-wide climate target covering the whole economy. It is thus relevant for all businesses and sectors since it will set the pace of the transition to 2050.
Directive establishing a Head Office Tax system for micro, small and medium sized enterprises	HOT (BEFIT)	SWD(2023) 302 final	09.12.2023	DG TAXUD	The objective of the HOT initiative is to reduce tax compliance costs for SMEs with a taxable presence abroad. It also aims at encouraging cross-border expansion of SMEs; and ensuring a level playing field for the participation of SMEs in the internal market.

<p>Directive harmonising certain aspects of insolvency law</p>	<p>Insolvency Law</p>	<p>SWD(2022) 395 final</p>	<p>07.12.2022</p>	<p>DG JUST & DG FISMA</p>	<p>The main part of insolvency cases concern SMEs. The lack of harmonised insolvency regimes in the EU poses a challenge to greater integration of EU's capital markets and thus to SME's financing options. According to the IA, Member States' insolvency laws vary extensively, and such significant differences constitute a serious obstacle to the capital markets union. Collecting information about other Member States' insolvency laws is costly and harms cross-border investment decisions. The IA also mentions the establishment of a special insolvency regime for micro- and small enterprises for higher efficiency of insolvency proceedings.</p>
<p>Directive on adapting non-contractual civil liability rules to artificial intelligence</p>	<p>AI Liability</p>	<p>SWD(2022) 319 final</p>	<p>28.09.2022</p>	<p>DG JUST</p>	<p>The purpose of the proposal is to improve the functioning of the internal market by laying down uniform rules for certain aspects of non-contractual civil liability for damage caused with the involvement of AI systems. The AI Liability Directive will allow people harmed by software (AI software) to receive compensation from the software manufacturer. Providing harmonised rules should improve the way the internal market functions and bring cost savings, especially for SMEs, as the need for businesses to assess liability risks separately for each targeted market, and the related legal uncertainty and costs would be reduced.</p>

Directive on alternative dispute resolution for consumer disputes	ADR	SWD(2023) 335 final	10.17.2023	DG JUST	<p>Alternative dispute resolution (ADR) aims to ensure the solution of disputes between consumers and traders without them having to go to court. It can be a fast and cost-effective mechanism for dispute settlement and is generally supported by the business community, seeing benefits for SMEs. Most significant changes for SMEs in this initiative concern the aim to adapt ADR mechanisms to developments in digital markets (with online intermediaries), to widen the scope materially to pre-contractual information, and geographically to non-EU traders and introduce a duty to reply for traders. This will have significant impacts on SMEs, especially concerning administrative burdens. Also, Consumers and businesses increasingly use private systems not meeting the ADR Directive requirements (PODR), which this initiative aims to change.</p>
Directive on common rules promoting the repair of goods	Right to repair	SWD(2023) 59 final	22.03.2023	DG JUST	<p>SMEs are included in the scope of the initiative, as they account for the vast majority of businesses in the EU, especially in the repair sector. According to Eurostat data, in 2019 businesses with less than 250 employees accounted for 99.7% of all enterprises, 77% of aggregate turnover, 80% of value added and 89% of employment in the repair sector.</p>

Directive on improving and enforcing working conditions of trainees and combating regular employment relationships disguised as traineeships	Traineeship Directive	SWD(2024) 67 final	20.03.2024	DG EMPL	The Traineeship Directive proposes to improve working conditions for trainees, including pay, inclusiveness, and quality of traineeships in the EU. Due to the potential additional burden with regards to complex bureaucratic processes, financial burdens, and increase in workload, the proposal has a direct impact on businesses.
Directive on packaging and packaging waste	Packaging waste	SWD(2022) 384 final	30.11.2022	DG ENV	SMEs make up the majority of waste recovery operators. The economic impacts assessed include costs and benefits, and administrative burden (in particular on SMEs and public authorities).
Directive on the energy performance of buildings (recast)	EPBD	SWD(2021) 453 final	15.12.2021	DG ENER	Increasing renovation rates will inject a stimulus in the construction sector and the wider economy with positive impacts on both GDP and jobs, in particular in local SMEs. More than 90% of companies in the building sector are SMEs. Increased deployment of renewable energy in buildings will also benefit SMEs, which operate most of the value chain of deploying renewable energy technology, in particular solar panels.

<p>Directive to further expanding and upgrading the use of digital tools and processes in company law</p>	<p>Digital Company Law</p>	<p>SWD(2023)178 final</p>	<p>29.03.2023</p>	<p>DG JUST</p>	<p>The initiative aims to increase further the availability and reliability of company information in business registers. Especially at cross-border level, it strives to simplify the access to the information in business registers, by using digital tools and processes. The initiative should stimulate cross-border trade, services and investment flows and thus contribute to competitiveness and growth in the single market. These measures will apply to around 16 million limited liability companies and 2 million partnerships in the EU. As SMEs account for 98-99% of limited liability companies in the EU and around 40% of SMEs engage in cross-border activities, they will particularly benefit from the expected reduction in administrative burdens. The measures, including the resulting increased legal certainty, will be strongly beneficial to SMEs.</p>
<p>Directive on waste and repealing certain Directives</p>	<p>EU Waste Framework</p>	<p>SWD(2023)421</p>	<p>05.07.2023</p>	<p>DG ENV</p>	<p>The Waste Framework Directive sets the basic concepts and definitions related to waste management, including definitions of waste, recycling and recovery, and the waste hierarchy. The revision introduces new targets for Member States on textile and food waste. 99.7% of all textile businesses, and 99% of food and drink industry are SMEs.</p>

<p>Regulation establishing a framework for ensuring a secure and sustainable supply of critical raw materials</p>	<p>CRMA</p>	<p>SWD(2023) 161 final</p>	<p>16.03.2023</p>	<p>DG GROW</p>	<p>SMEs would particularly benefit from the enhanced availability of monitoring and information regarding the supply chains of critical and strategic raw materials, as they generally do not have the resources to invest into their own monitoring and risk preparedness systems. Particularly affected by the legislative initiative are businesses and SMEs in sectors along the CRM value chain and those who directly use them as inputs, such as junior miners, firms engaged in exploration or in the nascent industry of CRM recycling, that are often SMEs.</p>
<p>Regulation establishing a Single Market emergency instrument</p>	<p>SMEI</p>	<p>SWD(2022) 289 final</p>	<p>19.09.2022</p>	<p>DG JUST</p>	<p>This initiative, renamed Internal Market Emergency and Resilience Act (IMERA) later in the legislative cycle, is considered relevant for SMEs as they represent 99% of all EU companies. The initiative was included in the SME Filter. See Annex 7, SME test, p. 133/151 of the IA report</p>

Regulation establishing an EU Talent Pool	EU Talent Pool	SWD(2023) 717 final	15.11.2023	DG HOME	<p>The EU Talent Pool is highly relevant to SMEs, particularly in light of significant and enduring skills and labour shortages across Europe, that rank among the main concerns for SMEs. The EU talent pool aims at addressing existing and future skills shortages, including those linked to the green and digital transition. Offering a job matching platform and a wide range of personalised guidance and services would benefit businesses and in particular SMEs, as it would guarantee access to a wider pool of relevant jobseekers from outside the EU.</p>
Regulation establishing the Union Customs Code and the European Union Customs Authority	Customs Code	SWD(2023) 140 final	17.05.2023	DG TAXUD	<p>Imports of counterfeit and pirated products into the EU translate into a loss of profit, jobs and revenues of legitimate businesses. This issue is particularly relevant for SMEs. As an example, the SME relevance of the EU toy industry is notable: in 2020, 99% of the companies were SMEs, employing around two thirds of employees in the sector. This adds a clear SME dimension to the benefits of reducing unfair competition from non-compliant imports through better enforcement.</p>

Regulation on combating late payment in commercial transactions	Late Payment	SWD(2023) 314 final	12.09.2023	DG GROW	Companies from all size classes report regular and/or occasional occurrences of late payments. Late payments are an obstacle to growth, especially in micro-enterprises. Economic shocks and factors increasing uncertainty cause timeliness of payments to deteriorate. In particular, the culture of late payments - that still prevails in some EU member states - exposes SMEs where agreed periods or legal terms are not respected. This leads to a reduction in SME participation in public procurement.
Regulation on horizontal cybersecurity requirements for products with digital elements	Cyber Resilience Act	SWD(2022) 319 final	15.09.2022	DG CNECT	The proposal introduces common rules and requirements for manufacturers of products such as doorbells, smart home devices or WiFi routers sold in the EU market, as well as obligations for its importers and distributors to ensure that products with digital features are secure to use, resilient against cyber threats and provide sufficient information about their security properties. Since the large majority of companies operating in software and hardware markets are SMEs, we can consider the proposal as being relevant to SMEs.

Regulation on instant credit transfers in euro	Instant payments	SWD(2022) 546 final	26.10.2022	DG FISMA	The proposal will make instant payments fully available in euros to consumers and businesses in the EU and EEA countries, helping to reduce any excessive reliance on third-country financial institutions and infrastructures. Improving the possibilities to mobilise cash flows is expected to bring benefits for citizens and companies of all sizes and allow for innovative added value services.
Regulation on standard essential patents	Intellectual Property Framework	SWD(2023) 124 final	27.04.2023	DG GROW	Around 85% of the identified 3 800 potential SEP implementers are SMEs. Innovative SMEs have already been creating multiple applications using standards such as cellular, Wi-Fi, and NFC. Therefore, the question of how to license those technologies is relevant for such SMEs. This initiative addresses important problems SMEs face during SEP negotiations or business planning, such as the size of SEP portfolios, aggregate royalty, and FRAND determination. Additionally, the initiative offers to SME implementers reduced fees for the use of the competence centre's services and free advice on SEPs.

Regulation on the protection of geographical indications for craft and industrial products	CIGI	SWD(2022) 115 final	13.04.2022	DG GROW	SMEs are the main producers of local goods in the food sector, contributing to regional identities. This was also reflected in the public consultation, calling for input by producers: “individuals, companies, in particular SMEs, and associations or organisations.” and in the CfE: “As many of the operators are small producers of industrial and handicraft products, SMEs in particular should benefit from the GI protection.”
Regulation on the provision of digital euro services	Digital euro	SWD(2023) 233 final	28.06.2023	DG FISMA & DG ECFIN	The initiative is expected to give rise to more competition in the market for payments. Merchants throughout Europe, including many SMEs, would benefit from this in terms of lower costs and increased innovation. While there will be marginal one-off costs in the onboarding of the digital euro, the long-term benefits in terms of lower fees arising from increased competition in the EU payment market would outweigh them over time.
Regulation on the VAT administrative cooperation arrangements needed for the digital age	ViDA	SWD(2022) 393 final	08.12.2022	DG TAXUD	For digital reporting requirements, costs linked to the introduction of new reporting obligations are expected, but the reduction of ‘fragmentation costs’ related to differences in jurisdictions’ data reporting requirements would benefit all businesses, i.e. incl. SMEs.

<p>Regulation to make public capital markets in the Union more attractive for companies and to facilitate access to capital for small and medium-sized enterprises</p>	<p>Listing Act</p>	<p>SWD(2022) 762 final</p>	<p>07.12.2022</p>	<p>DG FISMA</p>	<p>The general objective of this initiative is to make listing of equity and non-equity securities on EU public markets more attractive for companies, in particular SMEs. This would make it easier for EU issuers to finance their activity and to grow, innovate and create jobs, while preserving a high level of investor protection and market integrity.</p>
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4 ANALYSIS

The role of the SME Filter

The SME Filter is a tool adopted by the European Commission that ranks EU initiatives according to their relevance to SMEs and signals those that are significant from an SME perspective. The network of SME envoys⁵ is responsible for filtering the legislative initiatives. Out of the 23 analysed IAs, more than half (12 out of 23 initiatives) were indicated as relevant or highly relevant in the SME Filter. Initiatives not included in the SME Filter have been launched prior to the launch of the SME filter tool and thus they could not have been filtered and included.

One of the assessed files (Intellectual Property Framework) explicitly states in its IA: “Initiatives that are listed in the SME filter will have to be accompanied by a proportionate SME test.” However, 2 of the 12 highly relevant or relevant files according to the SME Filter did not have a dedicated SME Test chapter in their IAs (Cyber Resilience Act, ViDA). Nevertheless, it is important to point out that the ViDA IA did include a thorough SME Test in the analysis of the policy options which allowed the legislative initiative to score the highest in our analysis, together with the EU Waste Framework. This point must be considered, while acknowledging that a dedicated SME Test chapter is not mandatory but would add to transparency and comprehensiveness. Thus, building on the example of the ViDA and working toward a clear presentation of the results, a revised SME Test could include different SME chapters for every policy option considered in the IA.

According to the better regulation toolbox, the IA report should indicate whether the initiative is considered ‘not relevant’, ‘relevant’ or ‘highly relevant’ for SMEs, drawing back on the suggestions from the SME Filter⁶. Overall, the lack of transparent presentation of the SME Filter results in the IAs themselves contributes to making the results of the SME Test less clear and more difficult to interpret. The fact that the results of the SME Filter are presented on the dedicated website does not change the lack of transparency within the IAs.

4.1 STEP 1: IDENTIFICATION OF AFFECTED BUSINESSES

The process of identifying the affected businesses is key to delivering proportionate and fit-for-purpose legislation. Its relevance is correctly highlighted in the European Commission’s guidelines and, in particular, in the first step of the SME Test. The first section of our analysis investigates whether businesses were exhaustively considered at the early stages of the consultative process with the Call for Evidence (CfE) and in the overall IA⁷.

According to the better regulation guidelines published in 2021: “*The CFE should already set an initial appreciation of the expected significant impacts on which stakeholders can provide feedback and input for the impact assessment.*”⁸

⁵ [SME Envoy network - European Commission.](#)

⁶ Better regulation toolbox (2023), p. 72.

⁷ With the revision of the European Commission’s better regulation guidelines in 2021, the Inception Impact Assessments (IIA) and Evaluation Roadmaps were replaced by the “Call for Evidence” (CfE).

⁸ [European Commission Better Regulation Toolbox, 2023.](#)

A Call for Evidence therefore sets out the key elements of the impact assessment, including the problem definition, objectives, policy options, and an initial appraisal of their expected impacts, data needs and consultation activities.⁹

The guiding questions used for assessing whether businesses are affected by a legislative initiative are the following:

- *Does the Call for Evidence (or Inception Impact Assessment, IIA) consider whether SMEs (including micro) are affected?*
- *Does the Impact Assessment consider whether SMEs (including micro) are affected?*
- *Is a certain group within the SME population identified (micro, small, or medium)?*

Does the Call for Evidence (or IIA) assess whether SMEs (and micro) are affected?

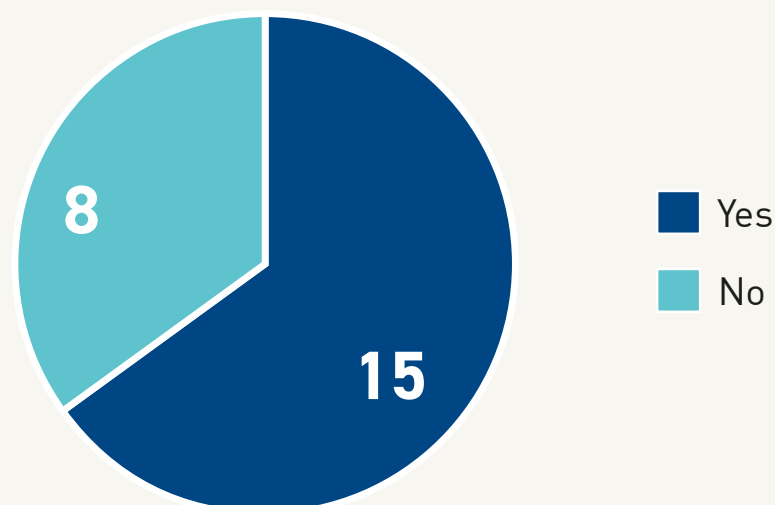
The analysis of 23 legislative initiatives concludes that two in three (15 out of 23) CfE assess whether SMEs are affected by the proposal. This result is in line with the analysis carried out in 2022 (18 out of 26 IIAs).

In light of this trend, the three organisations stress that better law-making begins at the early stage of the consultation process and therefore more attention is needed when considering the potential impact of new initiatives on SMEs. The CfE represents the first public communication of the Commission services to interested stakeholders concerning the expected law-making cycle. For this reason, CfE should clearly present the key elements of the planned initiative and in particular focus on the competitiveness aspects, evaluation of the SME framework, and factor in actions for simplification and burden reduction on businesses. Any limitation or constraints encountered in the evaluation process should be reported in the CfE which should also aim at closing potential knowledge gaps identified, in preparation for the open public consultation.

Moreover, CfE rarely include any references to micro businesses and whether they are affected by the initiative and often refer to the business community or economic operators as a large group without further distinction of subgroups. While it is not a mandatory requirement, such practice could improve the understanding of the initiative's impact from the early stages of the legislative process.

⁹ [European Commission Better Regulation Toolbox, 2023](#), p. 49

FIGURE 1. DOES THE CALL FOR EVIDENCE (OR IIA) ASSESS WHETHER SMES (AND MICRO) ARE AFFECTED?



Does the IA assess whether SMEs (and micro) are affected?

When it comes to the actual IA reports, the vast majority of them – 22 out of 23 – consider whether SMEs are affected by the proposal. The only exception observed in our analysis is the IA for the AI Liability Act which mentions that: “*Start-ups and other SMEs are likely to be significantly more affected by legal uncertainty and fragmentation than large companies (...)*”. The IA dedicates a short paragraph to acknowledge the general contribution of SMEs to the economy and outlines the barriers to competitiveness encountered by smaller businesses in relation to the fragmented AI landscape. Despite this, the IA delivers a rather superficial assessment of the impact of the proposal on SMEs.

The differentiation among the SME population according to different size classes continues to be an important shortcoming of the process behind legislative proposals. While this might be partially due to lack of data and information on SMEs, our analysis concludes that only 8 of 23 IAs provide clear differentiation according to the SME size classes (micro, small, medium) to identify whether SMEs (and micro) are among the affected businesses. This result goes in the opposite direction compared to the encouraging evidence from our previous report where 15 out of 26 IAs differentiated between distinct size classes within the SME category. Assumptions such as “*the proposal is expected to have a positive impact on SMEs*”¹⁰ – if not substantiated with empirical evidence – cannot be considered as evidence for good policy making. In some cases, such as in the EU Climate target 2040, the IAs distinguish between different sectors but they do not address the different sizes of SMEs.

¹⁰ Such as in the Insolvency Law, EPBD, EU Talent Pool, Traineeship Directive, Customs Code initiatives.

4.2 STEP 2: CONSULTATION OF SME STAKEHOLDERS

Holding exhaustive public consultation of stakeholders is essential to achieve informed decisions over potential policy options for new legislation. Based on the experience and the close link with businesses on the ground, stakeholders provide the necessary information on the practical impacts and applicability of legislation and propose alternative options more suitable to the needs of businesses, in particular SMEs. As suggested by the OECD¹¹, EU consultations should involve stakeholders earlier in the process, to discuss the who/what/when/how of the identified problem. This is particularly relevant considering the new commitment of the European Commission to reduce reporting obligations by 25%. All consultations should always provide for a systematic assessment of the compliance costs on businesses. This element needs to be a crucial factor in evaluating the policy options on the table and ensure that the preferred policy option also reflects the commitment to avoid unnecessary administrative burden on companies, without undermining the policy objective of the proposal.

The section below evaluates the quality of the consultations carried out by the European Commission according to four main aspects linked to the process: data collection, accessibility of the consultations, presentation of the results, and use of the consultation results. The four aspects were further broken down into a set of more detailed questions, presented below.

- *Was a 12-week open public consultation carried out?*
- *Does the consultation overlap with holiday periods? If yes, was the consultation period extended?*
- *Were the respondents able to identify themselves as SMEs/SME representatives?*
- *Were other consultation methods employed?*
- *Was the consultation available in all the EU 24 official languages (or 23 without Irish)?*
- *Were the views of SMEs adequately presented in the IA report?*
- *Does the presentation specifically refer to SME stakeholders?*
- *Are the consultation results used in the assessment of the impact of the policy options on SMEs?*

Based on the sum of the scores assigned to each of these criteria, the final score was identified according to a scale from zero points (very poor) to five points (very good).¹²

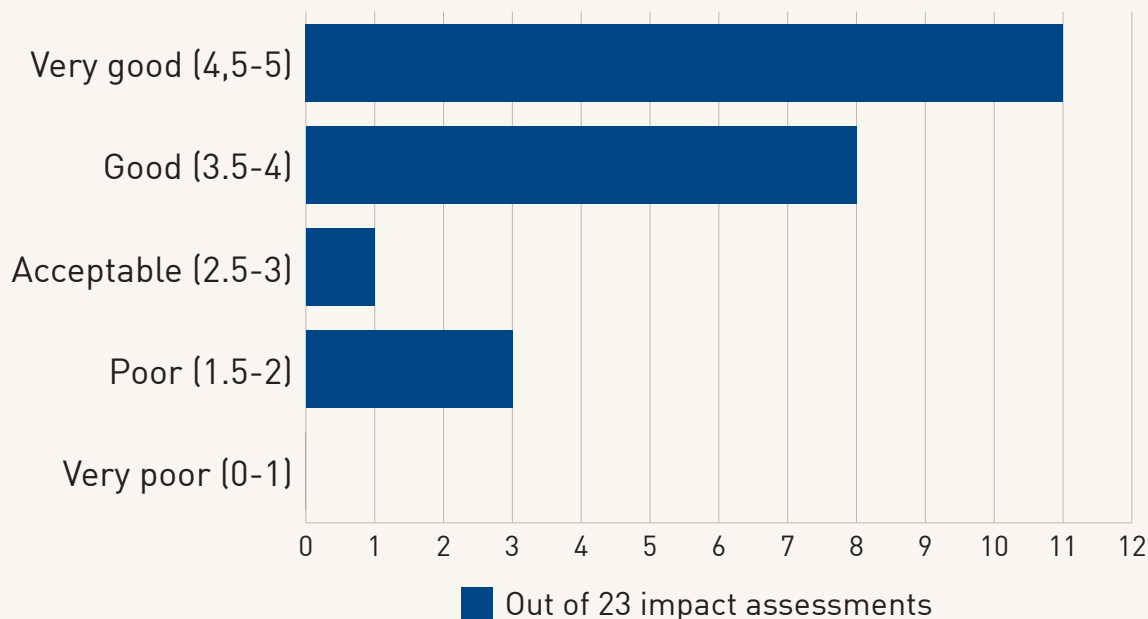
- 0 – 1 point: Very poor
- 1,5 – 2 points: Poor
- 2,5 – 3 points: Acceptable
- 3,5 – 4 points: Good
- 4,5 – 5 points: Very good

¹¹ [Better Regulation Practices across the European Union 2022 | OECD](#)

¹² For more information concerning the score of each element, please consult the methodology in Annex.

Comparing the scoring of the 23 IAs with the analysis carried out in 2022, it appears that the number of satisfactory consultations of SMEs and SME stakeholders has increased. However, a closer look at the results breakdown based on the questions presented above reveals issues that merit our attention as they are mainly linked to the collection of information needed in preparation for an exhaustive IA.

FIGURE 2. QUALITY OF THE CONSULTATION OF SME STAKEHOLDERS



Consultation period

Among the 23 legislative initiatives, only 17 respected the 12-week period for consultation. In six cases the temporal criterium was not respected with consultations open for:

- 4 weeks in the case of the SMEI;
- 8-9 weeks for the CRM Act, Late Payment, and Customs Code;
- 10 weeks for the Digital euro and the Cyber resilience Act.

In addition to this, more than half of the consultations (12 out of 23) overlapped with holiday periods (e.g. summer break, New Year’s break, or Easter). This is a very poor result as it strongly influences the capacity of SMEs and SME representatives to take part in the consultative process.

A much stronger commitment from the Commission services to avoid any consultation during those periods of inactivity would certainly have a beneficial effect on the quality of the consultations as they would likely result in more contributions.

FIGURE 3. WAS A 12-WEEK OPEN PUBLIC CONSULTATION CARRIED OUT?

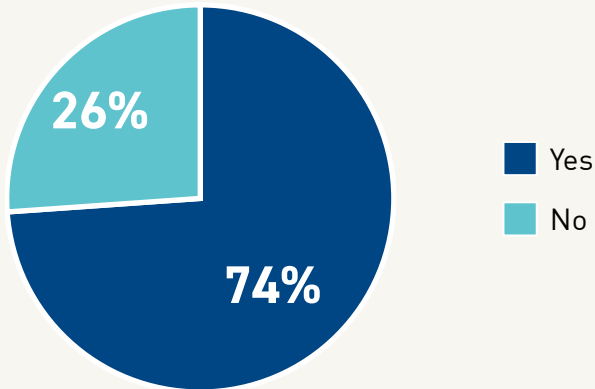
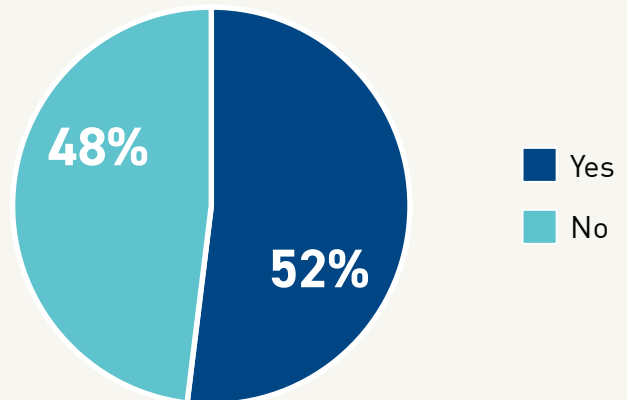
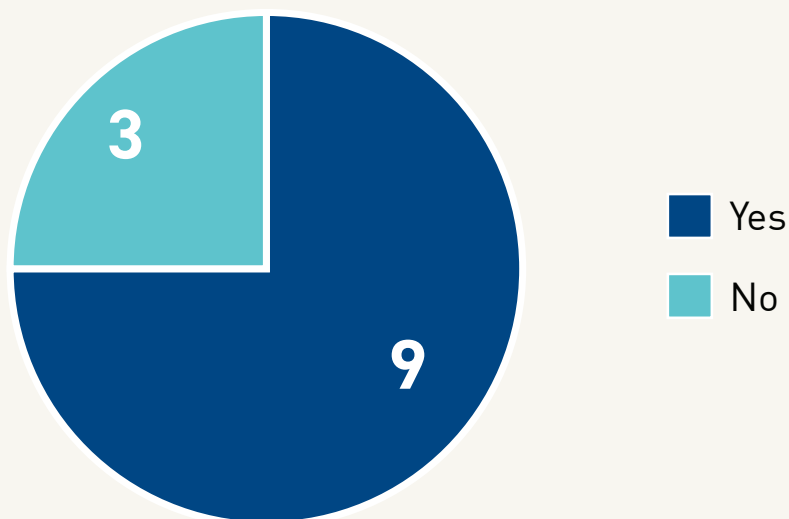


FIGURE 4. DOES THE CONSULTATION OVERLAP WITH HOLIDAY PERIODS?



Zooming in on the 12 consultations overlapping with holiday periods, we note that 9 of them were extended in order to ensure greater participation in the process. However, extending the consultations from the bare minimum of 12 weeks to 13 weeks (EU Waste Framework), or 14 weeks (Packaging waste, Listing Act, Insolvency Law, EU Talent Pool), or 15 weeks (Digital Company Law and HOT) will not necessarily bring the greater participation of stakeholders as expected. More fundamentally, the European Commission should always avoid holding consultations during holiday periods.

FIGURE 5. IS THE CONSULTATION PERIOD EXTENDED IF IT OVERLAPS WITH HOLIDAY PERIODS?



Were the respondents able to identify themselves as SMEs or SME representatives?

20 out of the 23 consultation questionnaires allowed the respondents to identify themselves as individual SMEs (by size) or SME representatives. With the adoption of the better regulation guidelines in 2021, this became a standard feature of the questionnaires proposed by the European Commission. Nevertheless, our analysis reveals that consultations held after the introduction of this feature – Digital Company Law, SMEI, and ADR initiatives – did not allow for this possibility. General expressions such as “company”, “business” and “business association” were used instead. This prevented SMEs and SME representatives from identifying themselves as such and consequently made it more difficult to provide more granular information concerning their respective SME categories, e.g. micro, small, or medium companies.

While not being part of the SME Test process nor of our methodology, we further delved into the 20 consultations where respondents were able to identify themselves as SMEs or SME representatives, to check whether different questionnaires for SMEs and their representatives were devised. This qualitative assessment concluded that it was the case only for a couple of initiatives. Despite not being officially public, the European Commission sent targeted requests for data to specific stakeholders as part of the consultation strategy for the Listing Act initiative. The IA for Intellectual Property Framework proposal states that the public consultation contained questions specifically addressed to SMEs.

This analysis does not take into account other methods of targeted consultation which are considered in the next section.

Were other consultation methods employed?

The better regulation toolbox published in 2023 p. 188, reads as follows: *“In addition to public consultations, consultation activities may involve targeted actions such as round table discussions, focus group meetings, hearings targeting SME representatives, SME panel consultations or specific consultations – carried out with the assistance of the Enterprise Europe Network – aimed at providing inputs into the ‘SME test’ 278. Whenever it is deemed useful and relevant, the start-up community should also be targeted by the consultation activities.”*

Whenever a legislative initiative is expected to impact considerably a segment of the economy, targeted consultation strategies are necessary. Starting from the assumption that open public consultations should be the norm and should always be held according to the standards discussed so far, targeted consultations could provide further evidence and support the European Commission in the preparation of the IA report.

Our analysis concludes that for the vast majority of the legislative initiatives (20 out of 23) the Commission services employed other consultation methods targeting SME representatives or SMEs, including SME panels. This result partially confirms that, since our previous analysis in 2022, the Commission services increased the number of targeted consultations. However, since our current analysis largely focuses on legislative initiatives considered “highly relevant” for SMEs, targeted consultations are considered as an integral part in order to achieve a satisfactory consultation and therefore are to be planned, as stated in the better regulation guidelines.

While it goes without saying that targeted consultations are relevant, open consultations should continue to represent the primary channel to collect wider input from citizens, entrepreneurs, business associations, academics, as well as Member State representatives and public authorities. Targeted consultations should therefore never replace open public consultations but, instead, should be used as a complementary tool. For the Traineeship Directive, an open

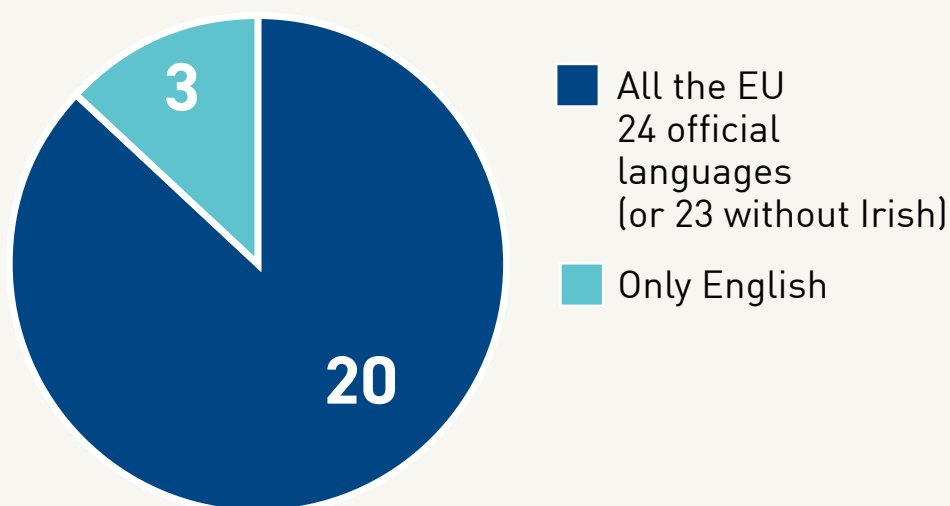
public consultation was not carried out as the European Commission held only a Social Partner consultation.

SME panel consultations with the support of the Enterprise Europe Network (EEN) were used on a couple of occasions (Late Payment, and the Traineeship Directive) to collect feedback directly from SMEs. The IA for the Cyber Resilience Act mentions that “it was not possible to carry out a proper SME panel consultation”.¹³ For the Instant Payment initiative, the public consultation was shared via the EEN to encourage SMEs participation. However, a dedicated SME panel was not foreseen. The SME Panel for the Late Payment initiative was carried out over a 7 week period, instead of the minimum of 8 weeks, and collected replies mainly from two member states. The better regulation guidelines should provide further guidance on how to make the SME Panel more representative.

Language regime

To ensure greater engagement in the consultative process, EU citizens and entrepreneurs should have access to questionnaires and information concerning new initiatives in all the EU languages. Out of 23 consultations, 20 of them included a questionnaire in all EU 24 official languages (or 23 excluding Irish). The result remarks a similar trend as in our previous analysis in 2022 where a very similar percentage of the consultations (85%, 22 out of 26) guaranteed full access to the questionnaires in all EU languages. In this analysis, three consultations (Digital Euro, Intellectual Property Framework¹⁴, SMEI) made use of a questionnaire only in English. The open public consultation for the HOT proposal was initially launched in English. Two weeks after its publication, all other languages became available on the “Have your Say” portal.

FIGURE 6. LANGUAGE REGIME OF THE OPEN PUBLIC CONSULTATIONS



¹³ P. 7, part 2 of the IA report for the European Cyber Resilience Act.

¹⁴ Translations in other EU official languages were uploaded in the European Commission system but – due to an error – were not available to respondents.

Were the views of SMEs presented in the IA report?

The analysis reveals a considerable improvement in this crucial aspect of the SME Test with 18 out of 23 IAs presenting the views of SMEs either in a dedicated section as part of the SME Test, or throughout the IA report, together with the views of other stakeholders. In the Digital Company Law initiative, there are several references to SMEs and to the benefits that such an initiative will bring to the 40% of SMEs that want to do cross-border trade. The CRM and EPBD IAs break down the open public consultation replies by companies and business organisations to better reflect on the answers provided by SMEs and their representatives.¹⁵

The ViDA IA goes even further by adequately presenting the number of responses according to the different SME categories (micro, small, and medium companies).

The ADR initiative, instead, does not present any clear distinction between SMEs and large companies with the IA report (part 1, p. 42) disregarding the concerns of companies, especially SMEs, and referring to “stakeholders’ view” only. The Packaging waste IA mainly refers to replies from “trade associations”.

While this IA on this initiative presents several references to the SMEs consulted and their concerns, the information is scattered throughout the report, making the evaluation of the impact on SMEs more difficult.

Overall, 19 IAs out of 23 refer to SME stakeholders resulting in an improvement, compared to the same aspect analysed in our previous edition of this report.¹⁶

While 20 out of the 23 IAs analysed refer to the position of SMEs and SME stakeholders, the information is sometimes found scattered throughout the IA and not reported for each policy option considered in the IA such as in the Packaging waste initiative.

Are the consultation results used in the assessment of the impact of the policy options on SMEs?

The findings of the open public (or targeted) consultations should always be used to better calibrate and evaluate the policy options. Our analysis concluded that 20 out of 23 IAs used the information collected during the consultation. However, the clarity and details of the information reported vary greatly among the 20 IAs. The EU Customs Code IA refers to SME respondents as “*Policy measures that received the highest support rates from SME respondents were (...)*”.¹⁷

The consultation strategy for the HOT proposal is another good example as it quantifies and evaluates the impacts of policy options on SMEs, taking into account the consultation results. Another example is the Digital Company Law IA which assesses the policy options based on a mixed methods approach in which the effectiveness, efficiency, and coherence of the policy options are graded on a scoring system that comprises qualitative, quantitative, and monetary data.¹⁸

The IA for Insolvency Law describes the key benefits and costs by stakeholder type - including SMEs – associated with the two policy options considered. The results are clearly indicated in two tables.¹⁹

¹⁵ Referring to one of the measures proposed, the EPBD IA mentions that “78% of SMEs support this measure”. P. 147 of IA report Annex.

¹⁶ In 2022, 15 out of 26 files specifically referred to SME stakeholders in their IA reports.

¹⁷ Customs Code, IA report p. 103-104.

¹⁸ The data employed for this analysis stems from various sources (public consultation, (...), previous IA, and workshops with stakeholders...) - See p.91/171 of the IA report.

¹⁹ IA report p. 55, Table 5 for Option 1 and p. 60, Table 7 for Option 2.

4.3 STEP 3: ASSESSMENT OF THE IMPACT ON SMES

European legislators are committed to delivering on the common goal of legislating “as simple and as clear as possible”, avoiding “overregulation and administrative burdens for (especially) SMEs”.²⁰ Measuring the potential impacts of legislative initiatives and adapting them accordingly, can help avoid regulatory burdens for SMEs. Thus, the European Commission announced in 2021 the intention to improve the analysis and reporting of proposals’ impacts on SMEs”.²¹

Compared to the SME Test Benchmark report 2022, there has been a significant improvement when it comes to assessing the impacts on SMEs. In this year’s analysis, 22 out of 23 IAs referred to differences between the impacts of legislative initiatives on SMEs and on large companies, compared to 14 out of 26 IAs in 2022. However, the presentation of the impact on SMEs is still not always clear. 16 out of 23 legislative initiatives have a dedicated SME Test chapter, this is not the case for the remaining 7. While the report acknowledges that this dedicated chapter is not mandatory, it is highly recommended for a transparent and comprehensive presentation of results.

Despite the European Commission stating in the 2023 better regulation toolbox that for highly relevant initiatives for SMEs, the impacts “should be analysed qualitatively and quantitatively for each policy option by business size (i.e. differentiating between micro, small, medium and large enterprises) to the extent possible.”²² a further subdivision between various groups of SMEs – micro-, small and medium sized companies – is only partly made in 17% of the initiatives (i.e. 4 out of the 23 IAs: Traineeships Directive, CIGI, EU Waste Framework, ViDA). Nevertheless, still a distinction between large companies and SMEs is made in the initiatives identified as relevant and highly relevant to SMEs. This is a positive finding when looking at the essence of the SME Test, which is to compare the expected impacts of the legislative proposal on SMEs against large companies. However, it must be kept in mind that the group of small and medium companies is heterogenous and that a further subdivision could prove useful in many cases.

In addition, out of the 12 initiatives being included in the SME Filter, this assessment was only reflected in 8 initiatives (not mentioned for EU climate target 2040, Cyber Resilience Act, Digital Euro, ViDA).

The scores for this step were given according to the methodology explained in the Annex and by considering the following elements:

- *Does the analysis distinguish the impact on SMEs from the impact on large companies?*
- *Does the analysis identify and measure the impact on each subgroup of the SME population (micro, small and medium-sized enterprises)?*
- *Is the impact on SMEs quantified or is the analysis purely qualitative? If there is no quantification, is an explanation provided?*
- *Is the impact on SMEs measured for all policy options, or only for the preferred one?*

²⁰ Interinstitutional Agreement on better Law-Making, Recital 2.

²¹ Better regulation toolbox 2023, p. 183.

²² Better regulation toolbox 2023, p. 189.

Does the analysis distinguish the impact on SMEs from the impact on large companies?

All initiatives referred to the differences between SMEs and large companies and almost all – 22 out of 23 initiatives – of them differentiated impacts between large companies and SMEs. The exception was the IA on Customs Code, arguing there were no significant impacts on SMEs to be expected. This number is a significant improvement compared to the results of the last report in 2022, where 14 out of 26 of IAs distinguished the impact on SMEs from the impact on large companies. However, there are differences in the depth of which the differences are considered. Indeed, in certain files such as ADR, the SME Test is only mentioned among the policy options, without further elaboration on SME specificities. The SME Test thus becomes a tick-the-box exercise. However, it is crucial to include a thorough assessment of impacts on SMEs, mentioning them without a clear assessment does not live up to the SME Test requirements. Interestingly, on another note, while generally distinguishing large companies and SMEs, the ViDA (PO 1) also compares measures for micro and small enterprises with measures for medium and large companies.

Overall, there is a general improvement on the differentiation of the impact on SMEs and large companies. That being said, there are still gaps on the quality of the assessment, taking into account SMEs characteristics and figures – to the extent possible. It remains crucial to highlight that underestimating potential impacts on SMEs with the simple justification that there are no significant impacts to be expected (such as in the Customs Code), cannot be identified as a proper SME Test with a clear differentiation between large companies and SMEs. The differentiation between large companies and SMEs and the separate impact measurement for SMEs help shed light on potential consequences of the legislative initiative for SMEs, such as effects on access to finance, other administrative or compliance costs, and employment. This, however, can only be the case when properly conducted, as it was done for CIGI or ViDA. For the EU climate target 2040, one of the reasons why the RSB issued its first negative opinion was that the impact on SMEs must be further assessed. This underlines the importance of an in-depth distinction between large companies and SMEs and the possible consequences.

Was the analysis on SMEs' impacts presented clearly?

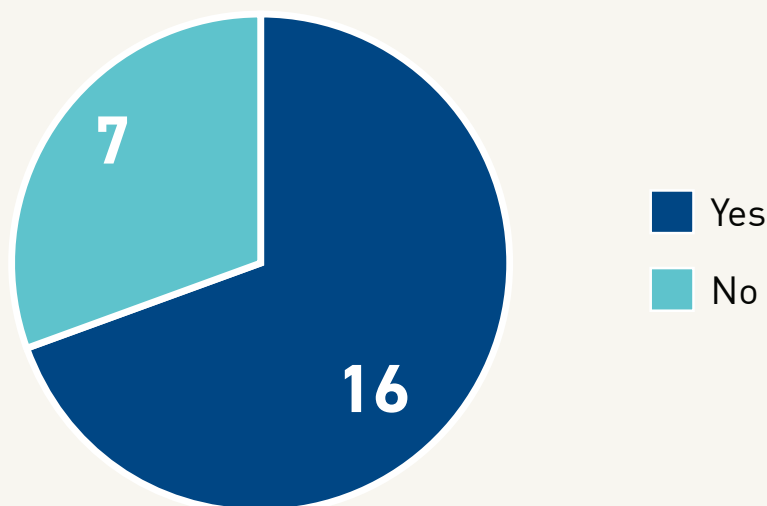
According to the better regulation guidelines, the IA report should summarise the findings of the IA in a “transparent, objective and balanced” way, to provide a good evidence base for the European Commission’s decision-making. For the presentation of the findings to be clear and concise, the guidelines lay out that annexes should contain the detailed and technical parts of the analysis, while the report should be “written with non-expert readers in mind”. The main report should not exceed 40 pages of text and can be accompanied by annexes as appropriate.²³ In most cases the main part of the report exceeds this page limit, the median amount being around 70 pages. Only in 4 out of 23 initiatives, the page number was around or not much above 40 pages (HOT, ADR, Digital Company Law, Packaging waste). Despite emphasising the need for clarity and preciseness, a lengthier report – if justified due to the content – can also achieve this goal, as long as it is well-structured and results are clearly presented.

What is even more important than length, is a clear presentation of results. However, only 16 out of 23 initiatives had a dedicated SME Test chapter. A clear presentation of results of the IA remains an important recommendation, already highlighted in our previous report. A negative example for the presentation of results is the AI Liability Directive, where the information is scattered throughout the report and impacts on SMEs are mentioned in some parts of the general analysis (e.g. on legal certainty, p 113f). In some cases, such as the CIGI and ViDA, the

²³ Better regulation guidelines 2021, p. 34.

results were not clearly presented in a dedicated chapter, despite being well analysed. Thus, it is interesting to note, that the quality of the assessment of impacts on SMEs does not always directly correlate with the quality of its presentation. The assessments for the initiatives of the CIGI and the ViDA were thoroughly done and also distinguished size-classes of SMEs. However, the findings were not clearly presented in a dedicated section. For the SMEI initiative, the RSB explicitly asked in its opinion for a clearer presentation of the results of the SME Test in the IA. For the Intellectual Property Framework initiative, the RSB asked for a clearer overview of all the measures to minimise the negative impacts on SMEs as well as a better description of the SME supporting measures when presenting the options and in the SME Test. In the case of the Insolvency Law initiative, the RSB found the SME Test missing and pointed that out accordingly. A clear presentation of findings and analysed impacts on SMEs remains a crucial part of the assessment, to ensure transparency of the legislative process.

FIGURE 7. WERE THE SME TEST RESULTS PRESENTED CLEARLY



Does the analysis of the impact identify and measure the impact on each subgroup of the SME population (micro, small and medium-sized enterprises)?

For most initiatives, company size matters when it comes to how impacts play out. This is why the better regulation toolbox states that IAs of policy options should consider company size, as a “one-size fits all approach for all SMEs might not be effective or efficient”.²⁴ However, out of the assessed 23 initiatives, only 4 differentiated (some) subgroups of SMEs (Traineeships Directive, CIGI, EU Waste Framework, ViDA). A division between sectors often seemed more intuitive (e.g. EU climate target 2040, EU Waste Framework, EPBD, or Late Payment). For example, CIGI considers small and micro enterprises as one group of producers with specific characteristics, putting special emphasis on micros and assesses the enforcement costs for one policy option (PO1, not the preferred one PO2) quantitatively for all company sizes separately (distinguishing between micro, small, medium-sized and large enterprises).

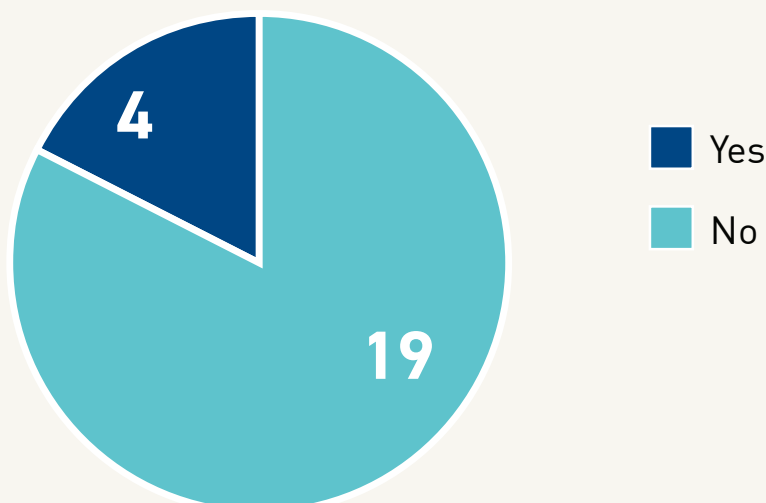
²⁴ Better regulation toolbox 2023, p. 189.

Another thorough distinction is for example found in the assessment of the ViDA when assessing the impacts of several policy options. Interestingly, the ViDA distinguishes micro and small enterprises from medium and large enterprises. Nevertheless, there seems to be no improvement in comparison to the last SME Test Benchmark report, which assessed that subgroups were distinguished especially for micro enterprises in 5 out of the 26 initiatives considered.

In three cases – EU Waste Framework, Packaging waste, CRM – micros are partly exempted. At this point, the principle of the better regulation toolbox 2023 should be emphasised: *“Exemptions should only be considered as the last mitigating measure.”*²⁵ However, when suggesting exemptions, it remains important to consider trickle-down effects. SMEs being part of supply chains, will always be indirectly impacted.

Suggesting exemptions just leads to fewer thoughts given to mitigating measures. This is especially the case for initiatives that come along with specific regimes for micro enterprises, such as the Insolvency Law initiative. While special regimes can be beneficial, it must be ensured to have proper guidance and support measures in place in these cases.

FIGURE 8. DOES THE ANALYSIS IDENTIFY AND MEASURE THE IMPACT ON EACH SUB-GROUP OF THE SME POPULATION?



Is the impact on SMEs quantified or is the analysis purely qualitative?

The quantification of impacts is a difficult task, which is why the better regulation guidelines and toolbox only ask for quantification where possible but do not require it. Expressly, the toolbox states that *“the assessment of SME impacts should, as far as possible, include quantitative estimates”*, thus acknowledging the complexity of the task.²⁶ While the findings of the last SME Test Benchmark report showed a quantitative analysis in 10 out of 26 IAs, this 2024 report found a quantitative analysis in 13 out of 23 IAs. This shows an improvement of quantification efforts in impact assessments.

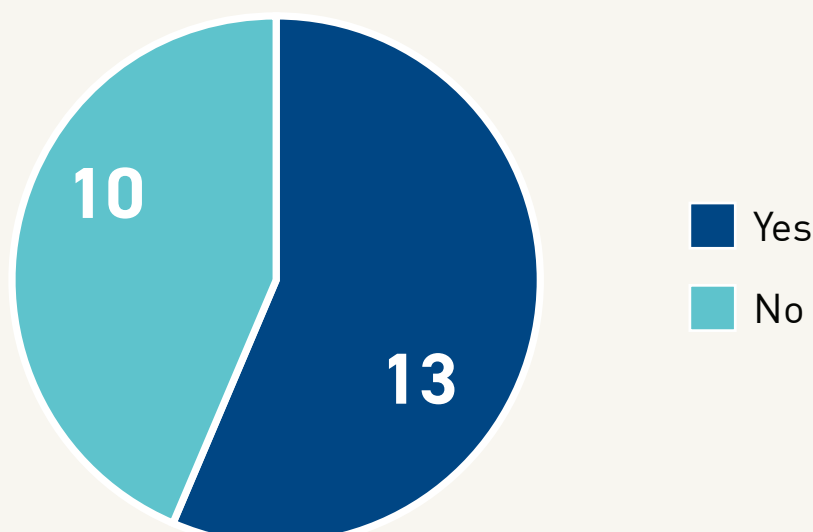
²⁵ Better regulation toolbox 2023, p. 184.

²⁶ Better regulation toolbox 2023, p. 72.

The IA for Late Payment states that the “impact of all policy options is described both qualitatively and quantitatively, where possible”, while assessing that some impacts are “not yet quantifiable”²⁷. Some IAs, such as the Digital Euro and AI Liability, clearly stated that for quantification of impacts more information or more assumptions (e.g. on technical specifications in the case of the Digital Euro) were needed. Thus, in the 10 cases, that used scarce to no quantitative data, at least 4 explained why quantifications were (partly) not possible.

In some cases, such as the AI Liability Directive and the EU Talent Pool, the RSB also explicitly asked to strengthen the quantification efforts (though for companies in general not for SMEs directly), or, as it was the case for the EU Waste Framework, at least better explain why certain aspects were not quantified.

FIGURE 9. IS THE IMPACT ON SMES QUANTIFIED?



Is the impact on SMEs measured for all policy options, or only for the preferred one?

The better regulation toolbox states for initiatives relevant for SMEs, that the costs and benefits of the respective initiatives must “*have to be analysed qualitatively for all policy options and – to the extent possible – quantitatively for the preferred option*”.²⁸ The impact on SMEs was measured for all policy options in 19 out of 23 initiatives. However, there remain significant differences between the assessments, most of them being qualitative, not quantitative. For the 4 initiatives not assessing the impacts for all policy options (Instant Payments, Digital Euro, EU Talent Pool, Customs Code), three were also included in the SME Filter and two of them also mentioned the relevance to SMEs in the IA (EU Talent Pool, Customs Code). However, their analysis of impacts on SMEs remains restricted to very general remarks, as for Instant Payments, or the preferred policy option only, as for EU Talent Pool.

²⁷ Late Payment, IA p. 39 and p. 114.

²⁸ Better regulation toolbox 2023, p. 189.

Despite the improvement, the quantitative assessment is still not done enough in the SME Test and for every policy option.

4.4 STEP 4: MINIMISING NEGATIVE IMPACTS ON SMES

According to the better regulation guidelines, when policy options impose a disproportionate burden on SMEs, compared to large companies, it is necessary to consider mitigating measures to alleviate such burden. However, the rationale of the “Think Small First” principle is to give full consideration at an early stage in the policy-making process to ensure that rules impacting businesses are developed from an SME perspective. For this reason, while the introduction of mitigating measures is relevant, it is crucial that the formulation of policy options takes into consideration SMEs’ needs, without imposing unnecessary and excessive burdens on them. A thorough application of steps 1 to 3 of the SME Test is therefore essential.

Given that a score is not attributed for this step, the analysis is limited to a statistical observation of whether and under which circumstances mitigating measures were proposed. While in some cases the need, or not, for mitigating measures is assessed and defined, in other cases this is not clear and therefore the need for such measures is debatable.

Mitigating measures planned

Out of 23 IAs analysed, 6 of them provide for some sort of mitigating measures for SMEs and/or micro-enterprises.

The IA of the Cyber Resilience Act overall reflects on the impact of the different policy options on SMEs and proposes several elements to off-set compliance costs for smaller manufacturers. In the Traineeship Directive, as SMEs are likely to be disproportionately affected, three mitigating measures are proposed for the preferred policy option, and in the Right to repair proposal, as some policy options would make SMEs face disproportionate adjustment and administrative costs relative to business revenues, the expected negative impact, e.g. on independent SME repairers, is mitigated via specific measures.

Other cases are the CRMA in which, although most of the measures are considered to have positive impact on SMEs, for those that could affect them negatively, specific exemptions are foreseen, such as one from reporting obligations. In the Listing Act, costs related to drawing up prospectuses are reduced, and in the ViDA an optional scheme for SMEs is foreseen.

As indicated in the introductory part of this section, the analysis of Step 4 is limited to a statistical observation of whether and under which circumstances mitigating measures are proposed. The assessment of such measures (e.g. whether they are appropriate, sufficient, or applicable) goes beyond the scope of the analysis.

Absence of, or unclear, mitigating measures

In the rest of the IAs analysed (17 out of 23), no mitigating measures are provided for or are unclearly defined. The reasons for the lack of such measures differ. In some cases, mitigating measures are not planned because SMEs are considered not to be, or not substantially, affected. For instance, this is the case of the Digital Company Law or Insolvency Law proposals.

In other cases, some analyses are partial, lack quantitative and/or qualitative evaluations, or focus only on benefits to SMEs, which case is not always backed by data. As an example, in the EU

Climate target for 2040 it was deemed difficult to assess whether a disproportionate negative impact on SMEs was likely, where the impact of this proposal is strongly dependent on the sector in which SMEs operate. In the EPBD, while some impact is acknowledged, it is not assessed in detail. As an example, the characteristics of SMEs are not elaborated or assessed in connection to the policy options which affects the feasibility of the options.

In other IAs analysed, despite the impact on SMEs was acknowledged - compared to large companies, as per better regulation guidelines - mitigating or alternative measures were not proposed. For instance, in the ADR, where certain measures, especially concerning administrative burden will impact SMEs more substantially, as they have less resources.

A lack of consideration of indirect impact was noted in the SMEI, in which the IA reports the difficulties that SMEs may face due to their limited resources to deal with the requests of the proposal, without comparing this clearly with larger companies though. Nevertheless, the IA concludes that no costs for SMEs are expected, and mitigating measures are not foreseen. In the case of the Packaging waste proposal, mitigating measures are unclear. Despite some impact on SMEs is outlined, it is concluded that in case a measure had significant negative impacts on SMEs, exemptions are included or foreseen. However, exemptions are proposed with an overall approach, and it is unclear whether they target SMEs.

Regulatory Scrutiny Board opinions

IAs should pay particular attention to SMEs if they are to achieve their objective of improving the business environment for SMEs. To achieve this goal, it is crucial to properly measure impacts on SMEs and undertake objective quality checks, which is the role of the Regulatory Scrutiny Board (RSB).²⁹ According to the Interinstitutional Agreement on better Law-Making, all opinions of the RSB should be published along with the final results of the IAs.³⁰ In the legislative initiatives assessed, the RSB opinion was indeed published for all IAs.

The RSB can issue three types of opinions on an IA: positive, positive with reservations, and negative.³¹ Out of the 23 IAs assessed, the RSB opinions gave a first positive opinion in 11 out of 23 IAs, while it was negative for 12 out of 23 IAs. Specifically, the RSB opinions were as follows:

- a first positive opinion in 2 out of 23 IAs,³²
- a first positive opinion with reservations in 9 out of 23 IAs,³³
- a negative first opinion and a second positive opinion in 3 out of 23 IAs,³⁴
- a negative first opinion and a second positive opinion with reservations in 8 out of 23 IAs,³⁵ and
- a negative first and second opinion for 1 out of 23 IAs (EPBD).

²⁹ Better regulation guidelines, p. 10.

³⁰ Interinstitutional Agreement on better Lawmaking, p. 13.

³¹ Better regulation guidelines, p. 11.

³² For IP new framework standard-essential patents, ADR.

³³ Late Payment, AI Liability Directive, Cyber Resilience Act, EU Talent Pool, HOT, Digital Company law, CIGI, ViDA, Listing Act.

³⁴ Digital Euro, Instant Payments, Insolvency Law.

³⁵ EU climate target 2040, Traineeships Directive, SMEI, EU waste Framework, Right to repair, Packaging Waste, CRMA, Customs Code.

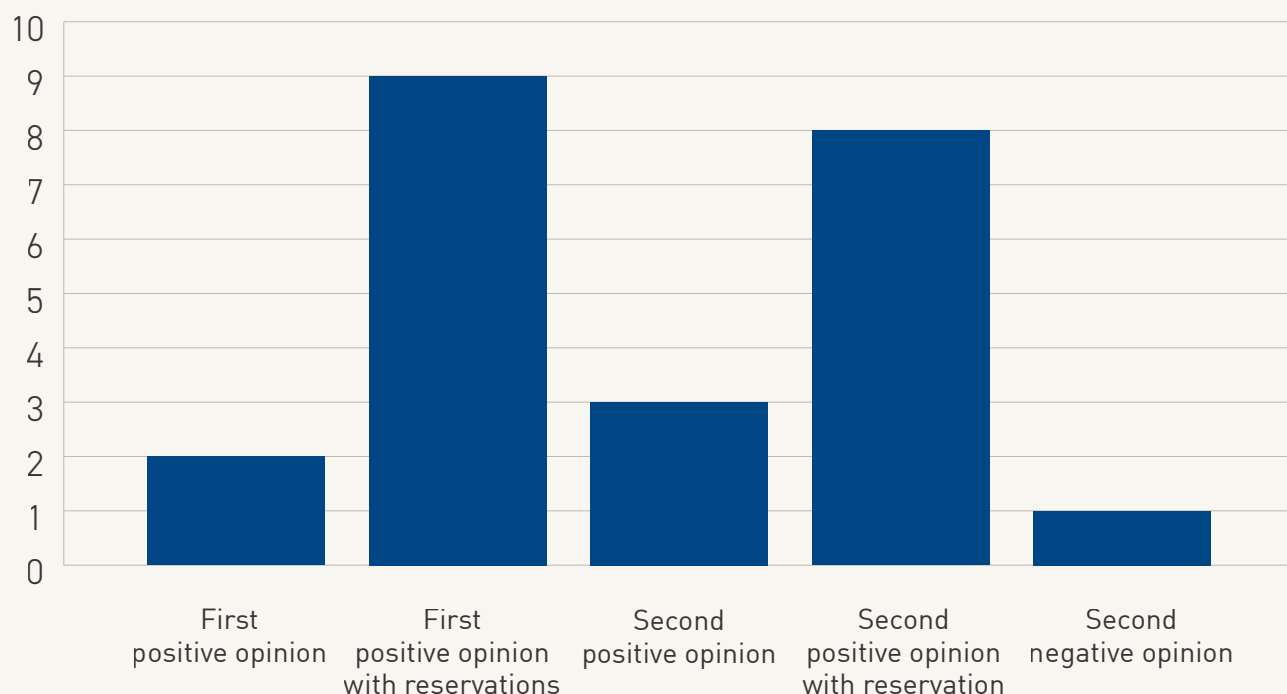
In 6 out of 12 initiatives included in the SME Filter, the RSB issued a negative first opinion and requested a revised IA, explicitly mentioning shortcomings and requiring improvements with regard to impacts on SMEs in four of them.³⁶

In 6 out of 12 initiatives included in the SME Filter, the RSB explicitly considered SMEs in its opinion. For example, the RSB saw SMEs' interests as insufficiently reflected in the Intellectual Property Framework and asked to improve the description of supporting measures for SMEs. In other cases, such as in the Cyber Resilience Act, the RSB asked to better outline the impacts on competitiveness and SMEs. In the opinion on the SMEI initiative, the RSB also asked for a clearer presentation of the results of the SME Test. Compared to our previous report, there is no significant increase concerning the number of RSB requests to better assess impacts on SMEs.

While the RSB opinions show that there is still room for improvement when it comes to IAs, it is positive to note that all of the final IAs address the remarks of the RSB. Almost all – except for the Cyber Resilience Act, which only briefly mentions the RSB procedure – address them in depth.

It stands out that the file with two negative opinions by the RSB nevertheless moved on in the legislative process, raising questions on the consideration given by the Commission services to the assessments carried out by the RSB. While the rules governing the role of the RSB allow for the Vice-President for Inter-institutional Relations and Foresight to submit the initiative for the College of Commissioners to decide whether or not to go ahead, the opinions of the RSB provide quality assurance of the Commission IAs. It is, therefore, crucial to respect the evaluations carried out by the RSB if the aim is to produce proportionate and well-informed legislation.

FIGURE 10. REGULATORY SCRUTINY BOARD OPINIONS ON THE 23 IAS



³⁶ Digital Euro, EU Climate target 2040, SMEI, EU Waste Framework, CRMA, Customs Code.

5 RECOMMENDATIONS

While the SME Test should be a mandatory element of the IAs, our analysis concludes that this is not yet the case. First, the European Commission should back its commitment to always perform IAs on all new initiatives with more systematic and concrete actions. This process could be reconsidered only in the very few cases where the proposal will not have any direct or indirect impact on SMEs.

At the same time, as the European Commission committed to simplifying and streamlining processes, each Directorate General should adopt a common SME Test template for every new legislative proposal. IA reports are currently expected to include the assessment of impacts on SMEs referring to the SME Test. However, having a dedicated section is not a mandatory procedure for the IA report. The adoption of a template for the SME Test chapter, drafted by the European Commission should be a practice to be considered by the Commission services. As highlighted in the Fit for Future opinion of 2023 on improving the SME Test, such a template would provide for a clear presentation of the IA results and a structured overview of the implications for SMEs deriving from a new proposal.

This practice, while it could be considered a minor improvement, would increase transparency during trilogues and improve the understanding of the impact on SMEs among the co-legislators.

As better law-making is a shared responsibility, the European Parliament and the Council of the European Union should adhere to better law-making principles also during the negotiation phase. More specifically, the coherence and impact of substantial amendments introduced by the co-legislators should be carefully evaluated: this was echoed by Enrico Letta and Mario Draghi in their recent high-level reports.

To increase transparency and gain a better understanding of the costs for the business community that a Commission proposal will entail, the calculations, the RSB's opinion, and the IA should be published immediately after the RSB has adopted its opinion. In any case, the draft IAs should be published before the proposals.

Concerning the four steps of the SME Test, the three organisations suggest the following recommendations.

STEP 1 – Identification of affected businesses

- **Calls for evidence (CfE) should always reflect on the potential impacts on SMEs and micro companies.** In addition, the CfE should report on the need for public or targeted consultations, including the timeline of the consultative process, and the expected availability of the questionnaire in all EU languages.
- **CfE must include a clear justification of the proposal based on evaluation.** As the initial step of the policymaking cycle, CfE is based on an earlier process carried out by each DG under the “evaluate first” principle. Such a process and its findings should be described in the CfE to justify a new initiative. Business organisations can help the European Commission on this as they can provide immediate feedback on whether an initiative would positively or negatively affect SMEs.
- **IAs should also deliver an accurate assessment by company size of the impact of the proposal on SMEs.** To better identify whether SMEs are among the affected businesses,

the IA report should better differentiate according to the SME size classes (micro, small, medium). Such differentiation must be supported by empirical evidence as it cannot be based on assumptions on the expected potential impact of a proposal on businesses.

STEP 2 – Consultation of SME stakeholders

- **Public consultation must respect the 12-week consultation period.** Public consultation should not be carried out during holiday periods (summer break, New Year’s break, or Easter). The better regulation guidelines should clearly define the periods for holding consultations and the periods to avoid. The 12-week calculation should exclude the period from mid-July to the end of August; New Year’s break goes from 24 December until 1 January.
- **Questionnaires must be concise and avoid leading questions to support the collection of impartial information.** For initiatives relevant to SMEs, open public consultations should consider simple, easy, and understandable questionnaires addressed to SMEs. In this regard, the RSB could be tasked with reviewing the questionnaire for an open public consultation – before it is held – to guarantee its impartiality. The RSB should also be tasked with reviewing the consultation process and ensuring that enough evidence is collected to perform a satisfactory fact-based IA.
- **Open public consultations and the criteria used to select the participants of a targeted consultation should be more transparent.** The consultations published on the “Have your Say” portal often lack relevant information that could help entrepreneurs, business representatives, or citizens to better understand the relevance of an initiative to SMEs. The “Have your Say” website should therefore include more information regarding the relevance of the initiative according to the inter-service group (ISG) discussions.
- **SME Panel consultation should lead to a clear picture.** They must aim at gaining a full overview over the SME perspective by respecting a proportionality principle in the replies in order to ensure full representativeness of the European perspective. This is particularly relevant in cases where a Regulation is under consideration as the legal instrument.
- **Open public consultations should be available in all EU languages as of day one of the process.** The information on the consultation availability in all EU languages should be clearly stated already in the CfE and reported in the IA report.

STEP 3 – Assessment of the impact on SMEs

- **The results of the SME Filter should be reflected and clearly displayed in the impact assessment.** Impact assessments should consider the relevance of a legislative initiative for SMEs. The revision of the better regulation guidelines introduced the SME Filter, which indicates the relevance, but still, IAs do not clearly display the result of the filtering process.
- **The impact on SMEs must be better quantified.** To avoid reducing the steps of the SME Test to a tick-the-box exercise, a thorough quantitative assessment of the impact on SMEs should be the norm, whenever possible.

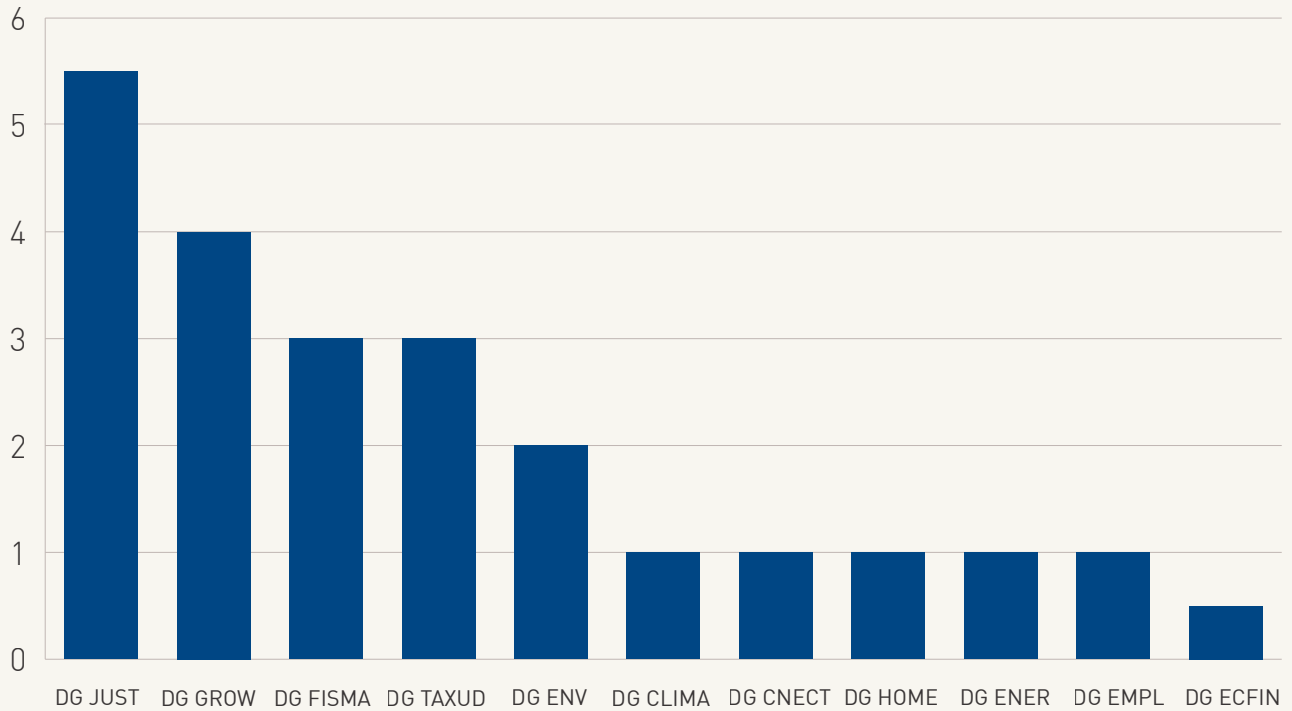
- **A clear differentiation between sub-groups when special regimes are put in place:** As SMEs have different capacities within their size-classes, it is key to clearly differentiate between subgroups, especially when special regimes are put in place such as for micros.

STEP 4 – Minimising negative impacts on SMEs

- **Mitigating measures should neither be a box ticking exercise nor be used as a last-resort offset tool.** While the introduction of mitigating measures is relevant, when justified, a thorough application of steps 1, 2, and 3 of the SME Test is instrumental in avoiding imposing unnecessary and excessive burdens on SMEs.
- **Mitigating measures must be clear, easy to apply, and fully tackle the issues identified.** Whenever direct or indirect disproportionate impact is acknowledged, it is key to have mitigating or alternative measures that bring clarity to SMEs. The measures must be specifically targeting SMEs and acknowledge their specificities (e.g. the sectors they operate in). Whether the proposed measures will fully support SMEs should be proved.
- **Impact on SMEs should be assessed in detail for effective mitigating measures.** In this regard, the availability of solid data is crucial. While it is understandable that the exercise of collecting relevant and timely information is a complex process, the utmost should be done to further collect usable elements. In this sense, further involvement of SME representatives should be considered.

ANNEX 1: DISTRIBUTION OF POLICY INITIATIVES

FIGURE 11. LEGISLATIVE INITIATIVES BY DG



Note: Figure 11 summarises the Directorate General leading the work for each of the legislative initiatives analysed. Whenever the work was coordinated by more than one DG, we used half point. This was the case for the Insolvency Law initiative (DG JUST & DG FISMA) and for the Digital Euro initiative (DG FISMA and DG ECFIN).

ANNEX 2: LEGISLATIVE FILES³⁷

COMMUNICATION ON EU CLIMATE TARGET FOR 2040 – OVERALL SCORE: 8.5/10

Identification of affected businesses:

All segments of the EU economy will be affected by the initiative. However, the initiative does not specifically target or have specific provisions for SMEs. The impact on SMEs depends on the sectors in which they operate. Accordingly, the IA distinguishes between different sectors, for example energy system costs for 2031-2040, and sectoral distribution of SMEs (IA p. 123). However, it does not differentiate among the different sizes of SMEs.

Consultation of SME stakeholders:

The open public consultation respected the 12 weeks (31 March - 23 June 2023) and language requirements (available in all EU languages). In the consultation, respondents were able to identify themselves as SMEs or SME representatives. In addition, a stakeholder consultation event was held on 9 June 2023 where 66 organisations were invited, including SMEs representatives. The IA report clearly presents the views of SMEs and SME stakeholders (p. 117 onward).

Assessment of the impact on SMEs:

The IA includes dedicated analysis for the impact of the various policy options on SMEs (p. 121). However, no distinction is made between the various subgroups of SMEs. There is only a distinction between sectors. Nevertheless, the IA report mentions that “SMEs will need dedicated support to access finance for sustainable investments and to navigate the relevant EU regulations”.

Minimising negative impacts on SMEs:

The Communication sets very general targets that may have an influence on other future legislation. For this reason, it is very difficult to assess whether a disproportionate negative impact on SMEs is likely. In general, the impact of the transition is strongly dependent on the sector in which SMEs operate.

³⁷ The overall score for each legislative initiatives is the sum of the scores for step 2 and step 3 of each IA. For more information, please refer to the methodology in Annex.

DIRECTIVE ESTABLISHING A HEAD OFFICE TAX SYSTEM FOR SMES – OVERALL SCORE: 8.5/10

Identification of affected businesses:

SMEs are in the scope of the proposal and will be directly impacted as it would reduce complexity and costs related to taxation. The IA assesses how SMEs will be affected, without making a difference between micro, small and medium.

Consultation of SME stakeholders:

The public consultation lasted 15 weeks as it was extended due to its overlapping with the New Year's break. Although it was first only available in English, the consultation became available in every EU language two weeks after the official launch. SMEs could identify themselves and there was a targeted consultation to gather SME views. Findings of SME surveys are taken into account in quantifying and evaluating the impacts of policy options.

Assessment of the impact on SMEs:

The analysis distinguishes between large companies and SMEs, but does not differentiate between micro, small and medium. The impact on SMEs was measured for every policy option.

Minimising negative impacts on SMEs:

No disproportionate impact was analysed, thus there is no mitigating measures foreseen.

DIRECTIVE HARMONISING CERTAIN ASPECTS OF INSOLVENCY LAW – OVERALL SCORE: 8.5/10

Identification of affected businesses:

SMEs are part of the scope of the proposal. While they are not specifically targeted, the proposal put forward a special regime for micro and small companies. The IA highlights that SMEs face a heightened risk of failure, which may lead to a business being wound down through an insolvency procedure.

Consultation of SME stakeholders:

The open public consultation was extended as it overlapped with New Year's break. The IA report distinguishes between micro, small, medium and large companies. The consultation was available in every EU language and SMEs views were presented in the report.

Assessment of the impact on SMEs:

The impact is assessed differently for micro and for other SMEs and is quantified. The impact is measured for every policy option

Minimising negative impacts on SMEs:

Disproportionate impact was not assessed for SMEs, thus no mitigating measures were foreseen.

DIRECTIVE ON ADAPTING NON-CONTRACTUAL CIVIL LIABILITY RULES TO AI – OVERALL SCORE: 6.5/10

Identification of affected businesses:

The IIA acknowledges that there will be an impact on SMEs. Legal uncertainty of outdated and unclear EU and national liability rules and divergent national approaches could leave producers, service providers and operators unable to assess the extent of their liability for products and services. This could create extra costs, stifle innovation and discourage investment, with a disproportionate impact on SMEs.

The IA mainly sees advantages of increased legal certainty and reduced fragmentation, but will also come with burdens, such as the reversed burden of proof, which is not mentioned.

Consultation of SME stakeholders:

A 12-week open public consultation was carried out. Despite no targeted SME questionnaires being devised, other relevant (SME) consultation methods were employed. SMEs' views are not adequately presented in the IA; however, some limited references were made to SMEs and SME stakeholders.

Assessment of the impact on SMEs:

The impact on SMEs is measured across all policy options, with a distinction made between SMEs and large companies. However, the analysis is not very comprehensive, but rather scattered throughout the chapter.

Minimising negative impacts on SMEs:

While the initiative would benefit SMEs, as legal certainty and reduced fragmentation would benefit start-ups and other SMEs in particular, the negative impact due to reversed burden of proof for AI manufacturers and developers are not considered. There are no mitigating measures foreseen.

DIRECTIVE ON ALTERNATIVE DISPUTE RESOLUTION FOR CONSUMER DISPUTES – OVERALL SCORE: 4.5/10

Identification of affected businesses:

The IA report mentions that in principle, SMEs are not likely to fall under the scope of the initiative. At the same time, the report also highlights that the initiative will have a strong impact on SME competitiveness. The IA recognises certain issues SMEs will face, notably the ‘naming and shaming of traders’ and focuses on benefits they could have, such as costs savings.

Consultation of SME stakeholders:

The public consultation lasted 12 weeks. SMEs were not able to identify themselves as the public consultation referred to “traders and trade associations”. The consultation was available in every EU language.

Assessment of the impact on SMEs:

The analysis takes into account the specific impact the proposal will have on SMEs as the main beneficiaries of the information provision cost savings both connected to the replacing of the ODR platform and ADR in general. However, the specific impact on SMEs was not quantified.

Minimising negative impacts on SMEs:

The report recognises certain measures, especially concerning administrative burden will impact SMEs more substantially, as they have less resources. However, the IA does not suggest any mitigating measures.

DIRECTIVE ON COMMON RULES PROMOTING THE REPAIR OF GOODS – OVERALL SCORE: 7.5 /10

Identification of affected businesses:

SMEs are affected by the initiative, as many of them operate in the sectors affected by the preferred policy option package, namely the repair sector and the manufacturing sector for certain products. Depending on the sector, SMEs will benefit from the initiative and/or face some costs.

Consultation of SME stakeholders:

A 12-week open public consultation was carried out and captured input from SMEs and their representative organisations. A business survey was also carried out in preparation for the IA, gathering responses mainly from SMEs (83% - 195 out of 235 respondents).

Assessment of the impact on SMEs:

The IA report provides data on the role of SMEs in the sectors affected by the initiative and on the impacts that the initiative would have on them. The business input in the IA report was to a large extent shaped by SMEs, as they represented the majority of the respondents. Although adjustment and administrative costs relative to business revenues are disproportionately higher for SMEs, the overall balance of costs and benefits under the preferred option is expected to be beneficial for SMEs.

Minimising negative impacts on SMEs:

Some policy options (1A, 5A, 5B) will make SMEs face adjustment and administrative costs relative to business revenues that are disproportionately higher than for other enterprises. The expected negative impact, e.g. on independent SME repairers, is mitigated via the measures promoting equal opportunities to repair among all repair service providers, such as the repair platform (P05B) and the repair quote (P06B).

DIRECTIVE ON IMPROVING AND ENFORCING WORKING CONDITIONS OF TRAINEES AND COMBATING REGULAR EMPLOYMENT RELATIONSHIPS DISGUISED AS TRAINEESHIPS – OVERALL SCORE: 7.5/10

Identification of affected businesses:

The IA states that SMEs are affected by the initiative. All measures considered have common economic costs for traineeship providers (including SMEs).

Consultation of SME stakeholders:

An open public consultation was not conducted, but the IA report mentions that a Social Partner consultation took place. Although respondents could identify themselves as SMEs or SME representatives, no separate questionnaires were developed for them. The impacts on SMEs were analysed qualitatively rather than quantitatively. The IA assesses the impacts on SMEs across all policy options.

Assessment of the impact on SMEs:

The IA measures the impact on SMEs, but it does not provide a comprehensive assessment of the impact on all subgroups.

Minimising negative impacts on SMEs:

SMEs are likely to be disproportionately affected. The costs, such as economic costs and those for monitoring and enforcement, are expected to be higher for SMEs compared to large companies. The preferred policy option includes three mitigating measures.

DIRECTIVE ON PACKAGING PACKAGING WASTE – OVERALL SCORE: 6 /10

Identification of affected businesses:

This proposal has an impact on the EU industry and SMEs that make up the majority of waste recovery operators. The economic impacts concern job creation, distribution of costs and benefits, and administrative burden, in particular on SMEs and public authorities.

Consultation of SME stakeholders:

A 14-week open public consultation was carried out and extended as it overlapped with a holiday period. In the IA, there are several references to SMEs views but are rather scattered throughout the report.

Assessment of the impact on SMEs:

The impact for SMEs is considered proportionate as reasonable efforts are required to reach the objectives of each measure under the preferred option. In order to facilitate compliance by SMEs with their obligations and requirements under the new Regulation, the IA states that guidance should be elaborated by the European Commission in consultation with stakeholders.

Minimising negative impacts on SMEs:

In case a measure had significant negative impacts on SMEs, exemptions were included or foreseen. However, exemptions are often used with an overall approach and it is unclear whether they target SMEs.

DIRECTIVE ON THE ENERGY PERFORMANCE OF BUILDINGS (RECAST) – OVERALL SCORE: 6.5/10

Identification of affected businesses:

The IA report takes into account the fact that SMEs play a key role in the construction environment and will thus be strongly affected by the proposal.

Consultation of SME stakeholders:

The open public consultation was held for 12 weeks and did not overlap with holidays. The questionnaire was available in all EU languages. Specific and targeted workshops were organised as part of the consultation strategy. SME views are clearly presented in the SME Test.

Assessment of the impact on SMEs:

While the impact is mentioned, it is not really looked into in detail. For instance, the characteristics of SMEs are not elaborated or assessed in connection to the policy options which affects the feasibility of the options. Its rather elaborating on all the positive possible effects without looking into the likeliness of these effects from the perspective of SMEs per sector/company size.

Minimising negative impacts on SMEs:

Disproportionate impact was not assessed for SMEs, thus no mitigating measures were foreseen.

DIRECTIVE TO FURTHER EXPANDING AND UPGRADING THE USE OF DIGITAL TOOLS AND PROCESSES IN COMPANY LAW – OVERALL SCORE: 8,5/10

Identification of affected businesses:

All companies fall under the scope of the proposal, which thus does not target specifically SMEs. However, it will have an important impact on SMEs in terms of compliance efforts. The analysis highlights mainly the advantages of the initiative for SMEs without specifying what compliance costs/efforts it would imply.

Consultation of SME stakeholders:

The open public consultation lasted 15 weeks, as it was extended due to New Year's break and was available in every EU language. Although SMEs could not identify themselves, there was an SME panel consultation. The IA refers a lot to the benefit the proposal would bring to SMEs but does not refer that much to SMEs views in particular, but to businesses in general. However, the IA gives a qualitative overview of the impact on SMEs.

Assessment of the impact on SMEs:

The IA assesses the benefits the proposal would have on SMEs, quantify how many SMEs could benefit from it but does not quantify costs.

Minimising negative impacts on SMEs:

No disproportionate impact was analysed, so no mitigating measures were foreseen.

DIRECTIVE ON WASTE REPEALING CERTAIN DIRECTIVES – OVERALL SCORE: 9.5/10

Identification of affected businesses:

SMEs are not within the scope and will be concerned indirectly through the setup of extended producer responsibility schemes (EPRs). SMEs explained they find EPRs rather difficult to handle, and the administrative burden related to waste legislation not proportionate.

Consultation of SME stakeholders:

The public consultation lasted 12 weeks and was not extended although it overlapped with summer, until 24 August. It was accessible in every EU language and SMEs were able to identify themselves. The IA referred specifically to SME stakeholders in specific sectors and both quantified and qualified the impact on SMEs.

Assessment of the impact on SMEs:

The impact was analysed differently for large companies and for SMEs and differentiated between micro and other SMEs. The impact was quantified for specific sectors and every policy options.

Minimising negative impacts on SMEs:

No disproportionate impact was foreseen for SMEs thus no mitigating measures were foreseen.

REGULATION ESTABLISHING A FRAMEWORK FOR ENSURING A SECURE AND SUSTAINABLE SUPPLY OF CRITICAL RAW MATERIALS – OVERALL SCORE: 6.5 /10

Identification of affected businesses:

SMEs should feel the positive effects of a more stable supply of critical raw materials. Particularly affected by the legislative initiative are businesses and SMEs in sectors along the CRM value chain and those who directly use them as inputs. Most of the measures discussed in this Impact Assessment have positive impact on SMEs, however some could affect them negatively.

Consultation of SME stakeholders:

An 8-week only open public consultation was carried out. Respondents were able to identify themselves as SMEs or SME representatives, and of 81 businesses that replied to the consultation 32 were SMEs. The results were used in the assessment of the impact of the policy options on SMEs.

Assessment of the impact on SMEs:

The IA provides some explanation which also measures the impact on SMEs, which is mostly considered positive for them. However, this lacks a detailed analysis. The IA analyses the 3 POs including impact on SMEs, but the SME Test only refers to the preferred option (PO2).

Minimising negative impacts on SMEs:

Although most of the measures discussed in the IA are considered to have positive impact on SMEs, there are some that could affect them negatively. Therefore, specific exemptions for SMEs are foreseen, such as one from reporting obligations.

REGULATION ESTABLISHING A SINGLE MARKET EMERGENCY INSTRUMENT – OVERALL SCORE: 4.5/10

Identification of affected businesses:

SMEs are within the scope of the proposal. Although they are not specifically targeted, they will be strongly impacted by the legislation. The IA assesses whether SMEs are affected.

Consultation of SME stakeholders:

The public consultation was open for only 4 weeks. SMEs could not identify themselves and no other consultation methods were employed. The consultation was not available in every EU language. However, the views of SMEs were quite adequately presented in the IA report for every policy option envisaged.

Assessment of the impact on SMEs:

The IA takes into account how SMEs will be impacted based on their resources and limited capacities to deal with urgent request, but the impact was not quantified.

Minimising negative impacts on SMEs:

No disproportionate impact was analysed, so no mitigating measures were foreseen.

REGULATION ESTABLISHING AN EU TALENT POOL – OVERALL SCORE: 7.5/10

Identification of affected businesses:

The IA mentions that the initiative is expected to have a positive economic impact. It should make the EU more competitive at a global level, which will benefit EU companies; including SMEs. The envisaged support to international recruitment would be particularly beneficial for SMEs as they are likely to bear a disproportionate burden when hiring TCNs in comparison to large enterprises due to more limited resources.

Consultation of SME stakeholders:

The consultation was open for stakeholder feedback for 14 weeks (extended due to New Year's break). To ensure that the views of SMEs are taken into account, additional consultation methods were employed, including meetings with target groups. Separate questionnaires were also created for SMEs and SME representatives.

Assessment of the impact on SMEs:

The analysis differentiates the impact on SMEs from the impact on large companies. The envisaged support to international recruitment would be particularly beneficial for SMEs as they are likely to bear a disproportionate burden when hiring TCNs in comparison to large enterprises. The impact on SMEs is assessed only for the preferred option.

Minimising negative impacts on SMEs:

The initiative would benefit in particular SMEs and it would facilitate international recruitment and guarantee access to a wider pool of relevant job seekers from outside the EU. As no significant negative impact on SMEs is expected, no mitigating measures are deemed necessary.

REGULATION ESTABLISHING THE UNION CUSTOMS CODE AND THE EUROPEAN UNION CUSTOM AUTHORITY – OVERALL SCORE: 4 /10

Identification of affected businesses:

This initiative targets economic operators of all sizes as they come into contact with customs. As an indication, only among the companies having applied for the Authorised Economic Operator (AEO) scheme, 69.8% identify as either micro-, small or medium-sized enterprise (SME). In addition, those SMEs operators not benefiting from the AEO scheme would nevertheless enjoy the simplification measures applicable to all traders, such as pre-release of goods, single submission of data and data re-use.

Consultation of SME stakeholders:

The open public consultation was available 8 weeks and 5 days, which is a shorter period compared to the standard 12-week duration. According to the IA, this was justified by the limited time frame within which the initiative has to be finalised due to its politically sensitive character and relative urgency. The OPC was available in all the EU 24 official languages and the views of SMEs can be considered as adequately presented in the IA report.

Assessment of the impact on SMEs:

According to the IA, the reform of the customs union is not expected to generate any adverse effects on SMEs, but rather positive impact on businesses, including SMEs, not to create additional administrative burden. SMEs would benefit from the overall cost savings directly, where they complete customs formalities themselves, or indirectly, where their customs formality service providers are able to offer a lower-cost service. Due to lack of data, it was not possible to quantify the specific impact on SMEs.

Minimising negative impacts on SMEs:

Such measures were not foreseen as no particular adverse impact on SMEs could be identified.

REGULATION ON COMBATING LATE PAYMENT IN COMMERCIAL TRANSACTIONS – OVERALL SCORE: 7.5/10

Identification of affected businesses:

According to the CfE, the proposal's objective is to facilitate timely payments, by promoting the use of modern digital payment tools and building up an "SME-friendly" business environment, supportive of timely payment. The IA also reiterates that SMEs are within the scope of this legislative initiative and are also the intended main beneficiaries of this revision. This initiative is considered highly relevant for SMEs, as it affects all EU SMEs.

Consultation of SME stakeholders:

The open public consultation took place for 9 weeks (12 January 2023 – 17 March 2023) and was available in all EU 24 languages. Respondents were able to identify themselves as SMEs or SME representatives. The European Commission conducted an SME Panel as a targeted SME consultation. The results were used in the assessment of the impact of the policy options on SMEs.

Assessment of the impact on SMEs:

SMEs were "expected to be the main beneficiaries" of this initiative and the analysis distinguishes the impact on SMEs from the impact on large companies. However, the analysis of the impact partially identifies and measures the impact on each subgroup of the SME population (micro, small, and medium-sized enterprises). Overall, the impact on SMEs is measured for all policy options without, however, estimating what percentage of SMEs would benefit from the other policy options (p. 167 of IA).

Minimising negative impacts on SMEs:

The proposal received mixed feedback from both business and SME representatives. Despite the concerns raised, the IA concludes that policy options in this proposal have been designed with SMEs in mind and thus do not provide mitigating measures.

REGULATION ON HORIZONTAL CYBERSECURITY REQUIREMENTS FOR PRODUCTS WITH DIGITAL ELEMENTS – OVERALL SCORE: 7.5/10

Identification of affected businesses:

The IA indicates that, in terms of number of companies, the software industry is almost entirely composed of SMEs and that the respective turnover generated accounts for 41%. This shows the important relative weight of big market players that may constitute only 0.3% of enterprises in the market but generate 59% of revenue.

While the proposal applies to all companies regardless of their size, the RSB considered that the IA did not undertake a comprehensive analysis of the distributional impacts for each type of stakeholders, in particular, on SMEs. However, the IA does include some quantitative analyses e.g. tables 15 and 16 (p. 29 and 30 of the IA – part 2).

Consultation of SME stakeholders:

The open public consultation was carried out over a 10-week period from March 2022 in all EU languages and the respondents were able to identify themselves as SMEs or SME representatives. The consultation was disseminated in various Commission-sponsored networks and events. The IA mentions that it was not possible to carry out a proper SME panel consultation.

The views of the SMEs were adequately presented in the IA with multiple references, examples and quantitative analysis. The results of the consultation are also used to assess the impact in the various policy options even though it is not possible for instance “to calculate the risks of market fall out due to excessive compliance costs for the SMEs”.

Assessment of the impact on SMEs:

The IA provides a lengthy quantitative assessment on how SMEs, especially manufacturers, will be impacted by the initiative, both in terms of costs and benefits, even though it was not possible to calculate to every type of activity (SME distributors and retailers of products with digital elements could not be estimated). The IA indicates that SMEs as end-users of products with digital elements will be impacted. The financial capacity of SMEs to absorb one-off costs and fixed costs is reflected in the analysis as well as the possibility of additional compliance costs being necessary to bring the security level of products manufactured by SMEs to an adequate standard. The IA also presents a qualitative analysis containing considerations on how SMEs perceive cybersecurity in general, their limited capacities, skills level and how to ensure compliance with applicable legislation.

Minimising negative impacts on SMEs:

The IA overall reflects on the impact of the different policy options on SMEs and comes up with several elements to off-set compliance costs for smaller manufacturers.

REGULATION ON INSTANT CREDIT TRANSFERS IN EURO – OVERALL SCORE: 5/10

Identification of affected businesses:

The IA indicates that companies of all sizes are covered by the proposal. When it comes to compliance, the costs are negligible for corporate SMEs as recipients of the instant payment service. However, as PSP (payment service provider) they can be substantial but the IA identifies this as part of a fintech business growth strategy.

Consultation of SME stakeholders:

The open public consultation was carried out according to the appropriate timeframe and respondents were able to identify themselves as SMEs or SME representatives. However, the use of other consultation methods was rather limited and there are very short analysis taking into account the position of SMEs.

Assessment of the impact on SMEs:

The IA clearly states that SMEs are expected to be among the net gainers from this initiative, whether as users or as payment service providers/ fintech. However, it does not provide lengthy qualitative and quantitative analyses on its impact on SMEs. The RSB identifies the IA's failure in explaining the distributional impacts on businesses, including SMEs.

Minimising negative impacts on SMEs:

No mitigating measures were foreseen.

REGULATION ON STANDARDS ESSENTIAL PATENTS – OVERALL SCORE: 6.5/10

Identification of affected businesses:

The scope of the initiative comprises firms of all sizes, including SMEs. The initiative does not target SMEs specifically, but its (positive) impact on SMEs may be more substantial than that on larger firms. The IA does not differentiate certain group within the SME population (micro, small or medium).

Consultation of SME stakeholders:

The open public consultation was carried out from 14 February 2022 until 09 May 2022, respecting the 12 weeks requirement. Concerning the language requirement, the consultation was only available in English. The Annex 9 of the IA presents a summary of replies to the consultation and respondents' characteristics and the consultation results were used in the assessment of the impact of the policy options on SMEs.

Assessment of the impact on SMEs:

The analysis somewhat distinguishes the impact on SMEs from the impact on large companies and it is measured for all policy options. The SME Test also distinguishes between the impact on SMEs as owners of SEPs and the impact on SMEs as implementers of SEPs.

Minimising negative impacts on SMEs:

Step 4 of the SME Test, states that the initiative will have its biggest impact on SMEs on the implementer side, more specifically on downstream implementers (device makers). For those firms, the impact should largely be positive. The potential negative effect (i.e., that the simplification of licensing that the initiative entails may encourage more SEP holders to approach downstream SME implementers for royalties) could be mitigated by encouraging SEP holders to exempt SMEs from paying royalties or provide discounts to a certain annual production volume (PO1).

REGULATION ON THE PROTECTION OF GEOGRAPHICAL INDICATIONS FOR CRAFT AND INDUSTRIAL PRODUCTS – OVERALL SCORE: 4/10

Identification of affected businesses:

SMEs are within the scope of the proposal. Although not specifically targeted, they will benefit from the legislation and thus be significantly impacted. The IA recognise how SMEs will be affected, without making any difference between, micro, small and medium.

Consultation of SME stakeholders:

The public consultation was open for 12 weeks without overlapping with holidays and was accessible in every EU language. Specific consultation targeted SMEs, through workshops and interviews. SMEs could identify themselves and the IA does present in a clear way the views of SMEs, with a quantitative and qualitative analysis.

Assessment of the impact on SMEs:

The analysis makes no difference on the impact on SMEs and on large companies, neither within micro, small and medium companies. The qualitative and quantitative analysis are made in general, with no specific element on SMEs. Additionally, the impact was not measured for every policy option.

Minimising negative impacts on SMEs:

No disproportionate impact was analysed, thus there is no mitigating measures foreseen.

REGULATION ON THE PROVISION OF DIGITAL EURO SERVICES – OVERALL SCORE: 3.5/10

Identification of affected businesses:

The IA states that merchants throughout Europe, including many SMEs, would benefit from this initiative. However, the initiative does not specifically target SMEs. Despite this, impacts on SMEs are likely to be more substantial than on other companies, namely to get acquainted with handling digital euro payments and possible changes to internal systems.

Consultation of SME stakeholders:

The open public consultation was open for 10 weeks (30 June 2023 – 08 September 2023), overlapping with the summer period. The consultation was only available in English. In order to gain more technical insights, the European Central Bank and the European Commission organised targeted consultations.

Assessment of the impact on SMEs:

While the analysis distinguishes the impact on SMEs from the one on large companies for the preferred policy option (IA p. 99), it does not measure the impact on each subgroup of the SME population. Accordingly, the SME Test concludes that *“it is impossible at this stage to estimate these benefits quantitatively, especially for a specific subgroup like SMEs.”*

Minimising negative impacts on SMEs:

According to the IA, some SME merchants will have to face small one-off costs due to the requirement in the preferred option to establish mandatory acceptance. Other SMEs and microenterprises will be exempted from mandatory acceptance and will not be directly affected. This translates into the need for SMEs to invest in a new infrastructure and change their payment systems (from the already accepted electronic payment system to new ones - also considering not all SMEs accept electronic payments).

REGULATION ON THE VAT ADMINISTRATIVE COOPERATION ARRANGEMENTS NEEDED FOR THE DIGITAL AGE – OVERALL SCORE: 9.5 /10

Identification of affected businesses:

The introduction of Digital Reporting Requirements (DRR) will have a different impact for each type of business. The IA acknowledges that providing an additional analysis on the impacts on SMEs of the introduction of digital reporting at an EU level is necessary. SMEs are also identified as being impacted in relation to platform economy and VAT registration.

Consultation of SME stakeholders:

The open public consultation run for 15 weeks as it overlapped with a holiday period. It was available in all the EU 24 official languages. Targeted consultations were carried out including business federations and SMEs. The views of SMEs were adequately presented in the IA report.

Assessment of the impact on SMEs:

According to the IA, introducing an EU DRR generates costs for businesses. This burden will be higher for micro and small enterprises, to the extent that they are less likely to benefit from business automation and are less likely to operate cross-border. The IA outlines both the benefits and the costs for SMEs.

Minimising negative impacts on SMEs:

Due to the historical difficulties of ensuring compliance and the relatively high administrative burdens VAT registration on SMEs, an optional SME scheme, where Member States allow for small businesses to eschew some, or all of the burdens imposed on a business exists. In practice, businesses are not required to account for VAT on their sales, but neither can they deduct VAT on their purchases. The eligibility of a business to use an SME scheme is based on their annual turnover, with thresholds differing across Member States.

REGULATION TO MAKE PUBLIC CAPITAL MARKETS IN THE UNION MORE ATTRACTIVE FOR COMPANIES AND TO FACILITATE ACCESS TO CAPITAL FOR SMES – OVERALL SCORE: 8 /10

Identification of affected businesses:

This initiative, which impacts SMEs directly and indirectly, aims to facilitate access to public market financing for all companies, while in particular establishing a more proportionate regime for SMEs. For companies, especially SMEs, these requirements may imply in certain cases high administrative costs, thereby potentially reducing the relative benefits of listing. However, these requirements also carry important benefits.

Consultation of SME stakeholders:

The open public consultation run for 14 weeks as it overlapped with a holiday period. It was available in all the EU 24 official languages and the views of SMEs were adequately presented in the IA report.

Assessment of the impact on SMEs:

This initiative aims to make listing more attractive as an alternative source of financing for SMEs. While the scope of this initiative is broader than SMEs and SME growth markets, SMEs would benefit from lower costs of issuing financial instruments on public markets, from lower compliance costs when being listed on public markets and overall from the introduction of more proportionate rules specifically foreseen for SMEs.

Minimising negative impacts on SMEs:

SMEs face a disadvantage relative to large firms in using market funding. To mitigate this disadvantage, the preferred options in this impact assessment would facilitate the use of market funding by companies and especially SMEs. They would reduce SMEs' costs of drawing up prospectuses, their costs of complying with MAR and provide enhanced opportunities in some Member States to raise equity through the adoption of MVR share structures.

ANNEX 3: METHODOLOGY

The methodology is based on the European Commission's 2021 better regulation guidelines and the 2023 better regulation toolbox and follows the four steps of the SME Test:

1. Identification of affected businesses
2. Consultation of SME Stakeholders
3. Assessment of the impact on SMEs
4. Minimising negative impacts on SMEs

Before analysing the four steps of the SME Test, general aspects of the legislative initiatives and their relevance to SMEs are investigated according to the guiding questions below, in line with the better regulation toolbox (tool #23) and considerations. The guiding questions are answered according to a YES/NO basis and are not used as part of the assessment of the four steps of the SME Test.

- Are SMEs within the scope of the legislative initiative?
- Does the initiative specifically target SMEs?
- Will the SMEs be significantly impacted directly or indirectly by the legislative initiative?
- Are impacts on SMEs likely to be more substantial than on other companies, for example in terms of adverse effects?
- Are SMEs of all sizes (micro, small, medium) across the EU concerned by the initiative?
- Does the initiative have a very high impact on SMEs in terms of compliance efforts?
- Has the evaluation identified important problem(s) for SMEs such as high regulatory costs, a widespread lack of compliance, critical feedback from SMEs and their representative organisations, etc.

The main part of the analysis follows the four steps above.

Step 1 is assessed on a YES/NO basis and does not involve attributing points. Steps 2 and 3 are attributed a score ranging from 0 to 5, according to the scale reported below. 0.5 points were attributed to dossiers found to be in between two quality levels (e.g. between poor and acceptable or good and very good). The criteria used for each step are explained in the relevant sections below.

- 0 – 1 point: Very poor
- 1,5 – 2 points: Poor
- 2,5 – 3 points: Acceptable
- 3,5 – 4 points: Good
- 4,5 – 5 points: Very good

Step 4 does not involve attributing points. Instead, in the presence of adverse impacts on SMEs, this step involves verifying whether mitigating measures were proposed in the IAs. Step 4 must

be performed only in cases where the previous three steps have led to the conclusion that a disproportionate negative impact on SMEs is likely – when compared to large companies. While this information is not always clearly identifiable in the IAs, the analysis assesses the needs for mitigating measures according to a case-by-case approach. If the analysis of steps 1-3 has led to the conclusion that mitigating measures were needed, we will consider whether the IA presented them or not.

In conclusion, the total score for each dossier can thus range from 0 (minimum) to 10 (maximum).

Overall score:

0-2 points: extremely poor

3-5 points: poor

6 points: acceptable

7-8 points: good

9-10 points: very good

In addition, the analysis considers the role of the SME Filter in determining the relevance of initiatives for SMEs and the overall quality of IA with specific attention to the presentation of the results of the SME Test.

- Does any of the relevant documents clearly mention whether the initiative is relevant/highly relevant to SMEs? Yes/No
- Are the results of the SME Test presented in a clear way? Yes/No
- Are the results aggregated in an annex to the IA or are they scattered throughout? Yes/No
- Are the results mentioned in the explanatory memorandum of the proposed legislative initiative? Yes/No

Step 1 – Identification of affected businesses

This step of the SME Test should establish whether and which SMEs are among the affected population. According to the 2021 guidelines, if the preliminary assessment leads to the conclusion that one or more classes of SMEs are affected, further analysis should be carried out.

The elements taken into consideration include:

- Does the Call for Evidence (or IIA) assess whether SMEs (and micro) are affected?
- Does the IA assess whether SMEs (and micro) are affected?

In making the above determination:

- Is a certain group within the SME population identified (micro, small or medium)? Both direct or indirect effect should be considered (e.g. subcontracting, sectoral impact etc).

Step 2 – Consultation of SME Stakeholders

Data collection:

- Was a 12-week open public consultation carried out?
 - Is the consultation period extended if it overlaps with a holiday period?
- Were the respondents able to identify themselves as SMEs/SME representatives?
- Were other consultation methods employed (e.g. SME panels, round tables, focus groups, hearing targeted SME representatives, meetings with stakeholders)?

Accessibility of consultations:

- Was the consultation available in all the EU 24 official languages (or 23 without Irish)?

Presentation of results:

- Were the views of SMEs adequately presented in the IA report?
 - Does the presentation specifically refer to SME stakeholders?

Use of consultation results:

- Are the consultation results used in the assessment of the impact of the policy options on SMEs?

Based on these elements, points are attributed as follows, with a potential maximum score of five points and a minimum score of zero.

Was a 12-week open public consultation carried out?	1 point if yes, 0 otherwise
Were the respondents able to identify themselves as SMEs/SME representatives?	0,5 if yes, 0 otherwise
Were other methods employed to specifically consult SMEs?	0,5 if yes, 0 otherwise
Was the consultation available in all the EU 24 official languages (or 23 without Irish)?	1 if yes, 0 otherwise
Were the views of SMEs adequately presented in the IA report?	1 if yes, 0 otherwise
Are the consultation results used in the assessment of the impact of the policy options on SMEs?	1 if yes, 0 otherwise

Step 3 – Assessment of the impact on SMEs

- Does the analysis distinguish the impact on SMEs from the impact on large companies?
- Does the analysis of the impact identify a certain group of the SME population (micro, small and medium-sized enterprises)?
- Is the impact on SMEs quantified or is the analysis purely qualitative? If there is quantification, does it include both administrative and compliance costs? If there is no quantification, is an explanation provided?
- Is the impact on SMEs measured for all policy options, or only for the preferred one?

For initiatives relevant or highly relevant

- If a threshold is considered, are the effects assessed on the potential scaling-up of companies? If the policy options exempt SMEs, do they assess the risks of indirect impact on them? Do they propose additional measures to support SMEs' capacity to grow?

Based on these elements, points are attributed as follows, with a potential maximum score of five points and a minimum score of zero points.

Does the analysis distinguish the impact on SMEs from the impact on large companies?	1,5 if yes, 0 otherwise
Does the analysis distinguish between the different SME class sizes (micro, small and medium-sized enterprises)?	1 if yes, 0 otherwise
Are the impacts on SMEs quantified?	1 if yes, 0 otherwise
Is the impact on SMEs measured for all policy options?	1 if yes, 0 otherwise
If a threshold is considered, are the effects assessed on the potential scaling-up of companies?	0,5 if yes, 0 otherwise
If the policy options exempt SMEs, do they assess the risks of indirect impact on them? Do they propose additional measures to support SMEs' capacity to grow?	Yes/No

Step 4: Minimising negative impacts on SMEs

Step 4 should be carried out only in cases where the previous 3 steps have led to the conclusion that a disproportionate negative impact on SMEs is likely – when compared to large companies.

- Do you believe that, according to the previous 3 steps, a disproportionately negative impact on SMEs is likely – when compared to large companies? Yes/No

If a disproportionate negative impact on SMEs is likely:

- Are mitigating measures foreseen for the preferred option? Which ones? Yes/No
- Were mitigating measures proportionate/sufficient? Yes/No
- Is the use of mitigating measures explained/justified?

Lastly, the analysis considers the **opinions issued by the Regulatory Scrutiny Board** on the overall IA.

- RSB positive (positive with reservations) first opinion?
- RSB negative first opinion + positive (positive with reservations) second opinion?
- RSB negative first + negative second opinion?
- Did the RSB take into consideration how the SME Test was carried out before issuing a positive opinion?

