



**Better regulation in the EU –  
what should change from a business perspective**

A DIHK policy paper

**DIHK**

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## Contents

Better regulation in the EU - what should change from a business perspective .....	1
Impact assessments .....	2
Drafting the legislative proposal.....	3
Regulatory Scrutiny Board (RSB).....	5
From one in one out to one in two out .....	6
Consultations .....	7
Further legislative procedure: European Parliament .....	8
Further legislative procedure: Council.....	9
Final legislative text .....	9
Evaluation of laws .....	10
Reality checks and implementation dialogues .....	11
Strengthening reality checks through a structured implementation perspective throughout the entire legislative process.....	11

## Better regulation in the EU - what should change from a business perspective

Since 2015, the EU has introduced various measures to ensure good regulation, from impact assessments and the *one in one out principle* to the establishment of the *regulatory scrutiny board* and various forms of consultation. Nevertheless, the German business community continues to report that the regulatory burden is too heavy and that some regulations are difficult to implement (see [Business Barometer 2024](#)). Many laws required such a significant implementation effort that their application was postponed due to lengthy and unpredictable procedures (e.g., the EU Deforestation Regulation, EUDR) or that the laws had to be significantly amended shortly after their adoption (see omnibus packages). While businesses consider the omnibus initiatives to be urgently needed, it is clear that such corrective measures should not become the norm in hindsight, as they also create burdens for all parties involved and lead to planning uncertainties. Instead, practical and proportionate laws should be enacted from the outset.

In addition, the volume and complexity of legislation have increased in recent years. Maintaining this rapid pace increases the risk of inadequate impact assessments and inconsistent laws that impose disproportionate burdens on those affected, such as businesses. Regulatory activity should therefore be limited to what is strictly necessary and better prioritized.

A recent [Call for Evidence \(CfE\)](#) indicated that the *better regulation agenda/ better regulation toolbox* could be revised or made available in a summarised form in the future. The DIHK strongly advises against the reduction of certain steps within the better regulation approach, as the instruments have not been applied uniformly to date (e.g. [SME Test Benchmark 2024](#)). Only if all instruments in the *better regulation toolbox* are used uniformly, consistently and across institutions can it be evaluated whether the toolbox is working or whether adjustments need to be made. A reduction in the number of measures should be avoided at this stage.

The following section discusses the various steps involved in better regulation within the ordinary legislative process from the business community's perspective, always with the aim of enacting workable laws and avoiding unnecessary bureaucracy.

### Impact assessment (IA)

Thorough IAs are essential. Even if there are time constraints and momentum prevails, detailed IAs should be carried out. Missing or retrospective IAs, which are published when the legislative proposal is already available, can no longer improve the quality of legislative proposals and should therefore be avoided.<sup>1234</sup> There must be clarity regarding the quality, effectiveness and feasibility of legislation from the initial draft to the end of the legislative process. IAs must be written in a clear and understandable manner and published well in advance. This allows a wide range of stakeholders, including businesses, to learn about the potential burdens and legislative proposals they may face.

A thorough IA requires the consistent and uniform application of all its components, including the SME<sup>5</sup> test, the competitiveness test, and the innovation check. Particular attention should be paid to ensuring uniform application of tests that are primarily qualitative in nature, such as the innovation check; alternatively, supplementary quantitative assessment methods should be developed as part of the revision of the regulatory toolbox. The competitiveness test should also examine more closely what impact each legislative initiative has on the imports and exports of European companies. In addition, it should be examined in advance whether, in addition to SMEs, the specific—and often high-risk—requirements of startups and scale-ups can be taken into account in a differentiated manner in the impact assessments, particularly with regard to innovation dynamics, experimental testing environments (real-world laboratories), scalability, market access for innovative solutions, and a more nuanced approach to regulatory requirements based on the stage of a company's development.

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<sup>1</sup>Missing IA to COM(2021) 890 final: [EPRS\\_STU\(2023\)753156\\_EN.pdf](#)

<sup>2</sup>Missing IA on COM(2022)46: [Special report 12/2025 - The EU's strategy for microchips](#)

<sup>3</sup>Delayed IA to (COM(2023) 755): [EPRS\\_STU\(2025\)765787\\_EN.pdf](#)

<sup>4</sup>Further examples based on a question from MEPs: [Parliamentary question | Rules applied by the Commission to determine whether an impact assessment will precede a legislative proposal | E-000226/2025 | European Parliament](#)

<sup>5</sup> Small and medium sized enterprise

In general, approaches such as early reality checks and company visits can help ensure that draft legislation more accurately reflects reality. At the same time, regulatory approaches that are already in use in member states and are working well would come to light early on through such dialogues. The goal is not to expand the scope of the process, but to prevent enforcement and implementation problems down the line. This allows business perspectives to be incorporated from the very beginning and brings principles such as "think small first" or "simplicity by design" to life.

Furthermore, the IA should also examine which laws with similar objectives and obligations already exist (a so-called coherence check). It frequently happens that legislative proposals do not align with existing regulations or with parallel running legislative procedures. One reason for this is that different Directorates-General draft the proposals, which are then considered by different parliamentary committees and Council working groups (e.g., the Empowering Consumers Directive and the Green Claims Directive). This problem of inconsistency is also evident in consumer protection regulations, e.g., in the case of differing information requirements on the same topic. In this context, in particular, existing definitions from current laws should be used if they describe the same content; or, more specifically, it should be examined whether the existing legislation is sufficient or whether it merely needs to be amended.

In summary, IAs should be conducted in a standardized format for all economically significant legislative initiatives. In particular, this should address administrative burdens, transition costs, digital feasibility, impacts on SMEs, enforceability in the Member States, implications for competitiveness, and interactions with existing EU law.

#### Drafting the legislative proposal

When drafting specific legislation, lawmakers should always bear in mind that the law must also be implemented by businesses. This applies in general, but especially to SMEs as well as sole proprietorships and micro-enterprises—after all, over 90 percent of businesses operating in the EU fall into the SME category. Consequently, it remains unclear why these factors are often not taken into account and why, for example, negative trickle down effects must be addressed only after laws have been passed in the form of omnibus packages. Reappointing the SME Envoy (see Small Business Act), who ensures an SME-focused approach across the various directorates-general, can help in this regard, as can the announced introduction of SME-friendly provisions.<sup>6</sup> These should apply across all directorates-general and should also be taken into account by the co-legislators.

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<sup>6</sup> *Sme-friendly-provisions* are standard legal formulations that can be applied in legislation. They aim to reduce the burden on small and medium-sized enterprises through simplified requirements, less bureaucracy and practice-orientated guidelines. The aim is to strengthen the competitiveness of SMEs and ensure that they are not at a disadvantage compared to large companies.

The institutions involved in the legislative process should also thoroughly examine which reporting requirements are absolutely necessary to achieve the regulatory objective, so that these requirements—as well as obligations such as certifications and licensing—can be limited to what is strictly necessary. For example, the approximately 1,100 data points requested as part of sustainability reporting (CSRD, ESRS) certainly do not all contribute fully to achieving the regulatory objective.

Notifications are much easier for SMEs to manage than certifications, as they involve lower costs and do not require the involvement of third parties. In addition, care should be taken to ensure that the frequency of renewal for necessary documentation is appropriate. Standard digital solutions should also be used in this context in accordance with the “digital-by-default” principle.

In principle, longer transitional periods should be granted for the implementation of legislation at company level. This applies in particular in view of the fact that necessary IT systems often cannot be provided by the Commission or the national authorities in good time (e.g. [EUDR](#) or [CO2 border adjustment mechanism](#)). Longer transition periods should also be provided for product- and packaging-related requirements, since, particularly in the case of long-life products and packaging, production is carried out in bulk, and products manufactured in accordance with the old rules will remain available for an extended period. Furthermore, when calculating a reasonable transition period, the conclusion of the EU legislative process for a regulation should not be used as the basis; rather, the decisive date for the start of the period should be the adoption of the national implementing legislation. Only then can a company be certain, from a legal standpoint, which rules it must comply with. Furthermore, sunset clauses for technical elements in legislation (e.g. reviewing the validity of thresholds in line with inflation) should be applied more frequently. This would result in laws being more up-to-date.

When publishing the legislative proposal, the Commission should issue, in addition to an impact assessment, a checklist that outlines the extent to which the principles of “think small first,” “simplicity by design,” and “digital by default,” as well as the SME-friendly provisions, have been applied in the text. This checklist should be adopted by the Parliament and the Council, and in the event of deviations during the trilogue, explanations should be provided.

#### *Summary of the demands:*

- The European Commission should produce higher quality IAs for all economically relevant legislative initiatives.
- The consistent and standardised application of the instruments within the IA must be the rule.
- Legislative proposals should always be reviewed for consistency.
- The *think small first* principle must be thoroughly applied in all IAs.
- The use of SME-friendly provisions should be encouraged; in particular, care must be taken to limit certifications and licensing to a reasonable extent.
- Transition periods must be of an appropriate length.

#### Regulatory Scrutiny Board (RSB)

The RSB acts as the European Commission's independent quality control body for IAs and evaluations. Its main task is to ensure that policy proposals are based on solid facts, a sound methodology and a balanced assessment of policy options. Although a negative opinion from the RSB usually obliges the Commission to revise and resubmit its analysis, the board has no formal veto power. In practice, even repeated negative opinions do not prevent politically prioritised initiatives from being driven forward. Consequently, the effectiveness of the RSB as a quality control mechanism depends on the Commission's willingness to fully implement its recommendations. If a negative opinion is issued repeatedly, corrective action should generally be taken. In exceptional cases, a project should only be pursued if a published, substantiated justification for deviating from the opinion is provided. This justification should clearly outline which points of criticism have been addressed and the reasons why certain recommendations were not adopted.

The graphic below clearly shows that many of the IAs carried out are not of sufficient quality. On average, 48 per cent of the IAs submitted receive an initial negative opinion. That is almost half of all submissions. If the RSB is to prevail as the Commission's internal monitoring board, the Commission's own standards in terms of high-quality legislation should change so that it carries out its IAs more thoroughly from the outset and then follows the RSB's assessments. If the current constellation does not lead to an improvement in the quality of IAs and laws, another legal framework for the RSB could be considered.

Table 1: Overview of Board regulatory scrutiny work by year, 2016-2024

Second negative opinions classified under year of second opinion						
Year	Meetings	Cases	Negative first opinions		Negative second opinions	
Impact assessments						
2016	22	60	25	42 %	2	8 %
2017	23	53	23	43 %	2	9 %
2018	27	76	21	28 %	1	5 %
2019	9	1	1	100 %	0	0 %
2020	23	41	19	46 %	1	5 %
2021	27	83	31	37 %	2	6 %
2022	20	70	24	34 %	2	8 %
2023	20	50	21	42 %	0	0 %
2024°	16	3	2	67 %	0	0 %

Source: RSB Annual Report 2024

*Summary of the demands:*

- Laws with IAs that repeatedly receive negative opinions should not proceed to the legislative process.
- The points of criticism noted in the opinions should always be addressed by the Commission before a legislative proposal can move on to the legislative process.
- The institutional set-up and competences of the RSB should be conducive to its role.

**From one in one out to one in two out**

The *one in one out* principle (OIOO) has been in place at EU level since 2021. The *EU standard cost model* is used to estimate the bureaucratic burden in monetary terms as part of the IA. If a legislative proposal causes particularly high costs, another legislative proposal in the same policy area should compensate for this. However, the Commission's own statistics show that the principle is not applied consistently (see [Annual Burden Survey 2022](#)), but that many initiatives such as the EU Supply Chain Directive (CS3D) or the Ecodesign Regulation are listed with zero burden - a procedure that the *better regulation toolbox* allows if there is sufficient justification. This appears to have been the case for almost 50 per cent of initiatives in 2022. If the increase in new burdens is actually to be stopped, it should no longer be possible to exempt legislative initiatives from the OIOO principle.

There was no Annual Burden Survey for the years 2023 and 2024. From 2025, the so-called annual simplification reports were introduced, which each Commissioner and the Commission as a whole must submit. The transparent design of the Annual Burden Survey (so-called offsetting overview) was dispensed with. Even if the OIOO principle has weaknesses overall, burdens were more comprehensible in the context of the *offsetting overview*, which

is why they should be included in the simplification reports. This overview should also be made publicly available on a website and kept up to date.

Given that the OIOO principle, when applied consistently, is designed to keep the amount of burden at the same level, the principle should be extended to *one in two out*. Only then can the instrument have a real impact on reducing bureaucracy.

*Summary of the demands:*

- Legislative initiatives should no longer be exempt from the OIOO principle.
- The *offsetting overview* should be added to the simplification reports.
- The *one in one out* principle should be extended to *one in two out*.

## Consultations

Public consultations at EU level are an important instrument for involving all stakeholders such as companies in the legislative process. The consultation periods of 12 weeks are more generous in comparison to national association consultations, which enables a substantial involvement and consultation of member companies. The *have your say portal* contributes significantly to a more transparent consultation process. However, it is not clear how the feedback is weighted and utilised. The EU Commission should ensure greater transparency in this regard.

Consultations should only be initiated once all translations are available. Technical measures should be taken to ensure that consultation questionnaires can be downloaded as PDF files in languages other than English. This was not the case, for example, during the second round of consultation on the revision of the EU Public Procurement Directives in November 2025. The online questionnaire and the PDF questionnaire should be identical. When drafting the questions, care must be taken to ensure that they are neither ambiguous nor leading. It is also important to always include a free-text field for certain sets of questions, as it often happens that the questions do not allow for the options desired by companies—therefore, there must be room for answers that cannot be captured by the provided response options.

In addition, more time is needed for Calls for Evidence (CfE) so that organisations can consult their members comprehensively. In addition, a huge amount of data is already available through existing reporting obligations and public registers, which can be used for IAs on new legislation. If no data is generally available or can be collected, the law should either be postponed or prioritize phased regulation, pilot projects, evaluation clauses, or narrowly defined regulatory areas. Laws that are based on insufficient information can cause negative

externalities or lead to laws being designed in a way that is unrealistic and therefore cannot be implemented (see omnibus packages).

*Summary of the requirements:*

- Feedback on consultation processes should be presented more transparently.
- Consultations should only start when translations in all languages and standardised questionnaires are available.
- More than one month should be allowed for CfEs.
- If the data basis for an initiative is too poor, it should not result in legislation.

### Further legislative procedure: European Parliament

The instruments at Commission level set the course, but a law can only be designed well and proportionately if the European Parliament (EP) and the Council adhere to similar standards or include SME friendly provisions in the legislative process.

The EP has a number of staff within the European Parliamentary Research Service (EPRS, Directorate for Impact Assessment and Foresight) who can carry out an IA review at the request of the relevant committee. This is done regularly and is intended to help MEPs to better categorise the quality of the IAs.

In addition, there is the option of asking the EPRS to assess the bureaucratic burden in the case of substantial amendments, among other things. This can help MEPs to weigh up the extent to which the additional effort is in line with the regulatory objective and is therefore appropriate. From 2012-2019, there were eight IAs for *substantial amendments*. From 2019-2024, no committee requested a review of the *substantial amendments* (see [EPRS Briefing](#)). Although a significantly higher number of legislative acts were adopted in the last legislative period in particular than in previous legislative periods and the bureaucratic burden on companies remains high, the committees decided against reviews. The EPRS also describes in its briefing that, compared to previous legislatures during VDL I, requests for support to the EPRS fell by 21 per cent. If capacities are available for reviews and a data-supported decision-making aid can be created, these options should be utilised more frequently so that more practicable laws are passed in future that do not have to be corrected in omnibus procedures.

In addition, the following assessment should be presented and published for all amendments in the EP (and in the Council):

- ✓ The implementation costs increase compared to the proposal.
- ✓ The implementation costs decrease compared to the proposal.
- ✓ The implementation costs remain unchanged compared to the proposal.

#### *Summary of the requirements:*

- *Substantial amendments* should be reviewed in terms of their costs.
- All amendments should indicate whether they increase, reduce or leave the costs unchanged.

#### Further legislative procedure: Council

There is room for improvement regarding better regulation at the Council level. Member States should take a leading role in better regulation that is consistent with the messages conveyed in the Council conclusions. In addition to exchanging best practices among Member States, the legislative process should at a minimum include a thorough review of proposed amendments and their implications. The review of amendments in the Council should follow the scheme proposed above:

- ✓ Implementation costs increase compared to the proposal.
- ✓ The implementation costs decrease compared to the proposal.
- ✓ The implementation costs remain unchanged compared to the proposal.

#### *Summary of the demands:*

- Better regulation instruments should also be introduced in the Council and the consequences of Council proposals should be reliably examined.
- All amendments should indicate whether they increase, reduce or leave the costs unchanged.

#### Final legislative text

The costs for bureaucratic burdens, which are calculated as part of the IA, should be adjusted after the legislative process has been finalised. A legislative text changes significantly during the ordinary legislative procedure and often contains content that could not yet be taken into account in the IA. In order to do justice to these efforts, an official adjustment should be made in accordance with the proposal in the Letta report on *dynamic impact assessments*. Only in this way can reliable values be determined for instruments such as the OIOO principle and member states and companies receive cost estimates that are helpful in preparing for implementation.

Laws should be formulated in such a way that they are unambiguous and companies do not need a multitude of guidelines and legal interpretations. The EU and later also the member states should add a summarising one-pager (so-called legal compass) with obligations and corresponding deadlines to each law. The Czech Republic has already introduced such a system at national level (see [Bureaucracy Detox](#)). Sample texts, such as a sample cancellation policy, could also be included in the annex; this can assist companies in implementing the requirements.

Furthermore, delegated and implementing acts should be used only to a limited extent and exclusively as provided for in the Treaties: for non-essential provisions and clarifications regarding implementation. Essential obligations, definitions, thresholds, and reporting structures should, as a rule, be regulated in the basic legislative act itself, which is subject to regular stakeholder participation and consultation. Delegated and implementing acts should be limited to clearly defined technical details and adopted in a timely manner. Finally, appropriately generous transition periods should also be sought in this context. Economic planning certainty must always be ensured.

Ultimately, the existing gap between the goal of a functioning single market and its actual implementation in the Member States should be addressed more effectively. In practice, significant fragmentation persists, for example due to differing national interpretations and registration and reporting requirements. This leads to considerable administrative burdens and legal uncertainty, particularly for SMEs. Ultimately, the existing gap between the goal of a functioning single market and the reality must be closed. A one-to-one transposition of EU laws into national law is urgently needed—and “gold-plating” must be avoided.

### Evaluation of laws

Regular evaluation of EU laws is essential. The *refit programme*, which expired recently, provided an overview via the website, albeit only updated once a year. Such an overview no longer exists. The (re)introduction of a digital board would be particularly helpful for the history of reviews of definitions, such as the SME definition (2003).

In addition, EU laws should be evaluated regularly—ideally after they have been in effect for two to three years—in a transparent manner and within reasonable timeframes, using clearly defined, measurable criteria. If the intended objectives are not achieved, adjustments must be possible based on the respective evaluation. In particular, the scope of application, reporting frequencies, and data depth should be reviewed. It is important to ensure that changes are proportionate, announced well in advance, and accompanied by reasonable transition periods in order to provide businesses with planning certainty.

Adjustments should generally focus on improving the practicability of existing regulations. A tightening of requirements should only be considered in strictly limited exceptional cases where there is clear, evidence-based proof of their necessity. Priority should always be given to less burdensome measures.

Finally, feedback from the implementation dialogues should be incorporated transparently into the evaluation process.

Table 1: Overview of Board regulatory scrutiny work by year, 2016-2024						
Year	Second negative opinions classified under year of second opinion					
	Meetings	Cases	Negative first opinions		Negative second opinions	
Evaluations and Fitness Checks*						
2016*		7	-	-	-	-
2017		17	7	41%	0	0%
2018		11	3	27%	0	0%
2019		17	8	47%	0	0%
2020		13	4	31%	0	0%
2021		15	3	20%	0	0%
2022		8	0	0%	0	0%
2023		8	4	50%	0	0%
2024		19	10	53%	0	0%

Source: RSB Annual Report 2024

### Reality checks and implementation dialogues

The newly introduced reality checks/implementation dialogues with companies should be expanded, as they have been very well received so far. They could be further strengthened by applying a more structured implementation perspective as part of the existing processes. This should start with an early definition of the topic, the dates, the group of participants and the follow-up plan. Transparency is crucial - for example through a clear communication plan, regular updates and early information on the objectives and process of the dialogues. It is important to openly explain how feedback will be used and how results will be published. A digital portal could be used here as a central point of contact, supplemented by workshops, webinars and newsletters for up-to-date information (optionally in combination with the reinstatement of the refit portal). Finally, consideration should also be given to whether such stakeholder roundtables could be organised as part of the CfE.

A transparent feedback loop shows companies how their contributions are incorporated into the revision of legislation or the reasons why proposals are not considered or cannot be implemented.

### Strengthening reality checks through a structured implementation perspective throughout the entire legislative process

The recently introduced reality checks and implementation dialogues could be further strengthened by applying a more structured implementation perspective, building on existing better regulation tools without introducing additional procedural steps. In this context, an

analysis modelled on the "customer journey" can serve as a practical analytical approach to systematically structure feedback from practitioners on new initiatives.

Such an approach is not a new, stand-alone tool, but rather a methodological refinement of existing processes. It would help to organise stakeholder insights along the typical stages of implementing a piece of legislation, including the identification of obligations, interpretation of key provisions, operational and technical adjustments, reporting obligations and interaction with enforcement authorities.

Applying this perspective supports a more consistent assessment of the clarity, feasibility and proportionality of regulatory requirements, while being fully compatible with the Commission's impact assessment framework and respecting the division of competences between the EU and national levels. It can also be applied to different categories of addressees, thus contributing to enforceable and legally certain legislation for all stakeholders without slowing down decision-making processes or increasing the administrative burden.

## Contact person with contact details

### Sandra Zwick

Head of Unit European Policy, EU Financing Instruments and EU External Economic Assistance

Europe Division

[Zwick.sandra@dihk.de](mailto:Zwick.sandra@dihk.de)

+49 151 11314650

### Who we are:

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