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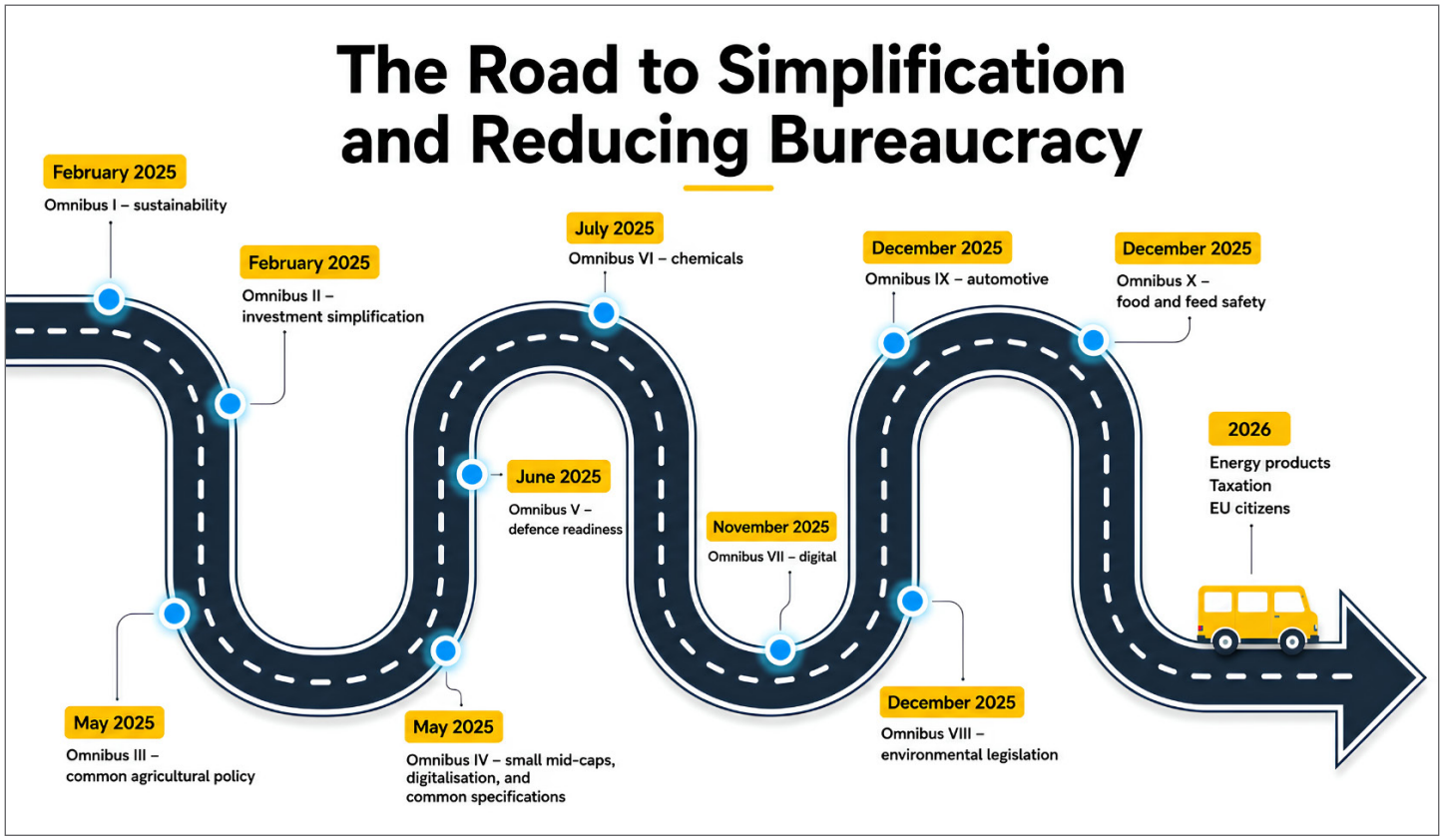
The call for less bureaucracy in the EU:

How to balance simplification and high standards?

Simplification as a guiding political principle

The European Commission aims to launch a “fleet of omnibuses” to simplify European Union (EU) legislation across a wide range of areas – a formulation repeatedly used by European Commission President Ursula von der Leyen. The Commission has since followed up these statements with concrete action: in 2025 alone, it presented a total of ten such Omnibus proposals, with more expected to follow. They cover a wide range of policy areas, from sustainability and digitalisation to artificial intelligence (AI), as well as agriculture, defence and chemicals.

These initiatives are part of a broader agenda to reduce administrative burdens, aiming to cut recurring administrative costs by 11.9 billion euros annually and provide tangible relief for businesses. At its core, the objective is to make existing rules easier to apply. One example concerns sustainability reporting requirements, which many companies perceive as particularly complex and resource intensive. The simplification agenda seeks to make these rules more practical while at the same time strengthening the competitiveness and resilience of the European economy.



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The so-called Omnibus packages are only one element of this broader approach. In parallel, the European Commission continues to revise individual pieces of legislation – often guided by the same principle of simplification. Examples include targeted amendments to the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR), as well as the planned revision of the REACH Regulation in the field of chemicals legislation.

However, these initiatives are not directly comparable. While all simplification proposals pursue a similar overarching objective, they differ significantly in their political background, legal approach and scope of amendments. At EU level, an “Omnibus” refers to a legislative procedure through which several existing EU legal acts are amended simultaneously. Such packages bundle thematically related provisions and adapt or partially repeal them collectively. The currently discussed amendments to the MDR and IVDR are not as far-reaching. They therefore do not qualify as Omnibus packages but rather as targeted adjustments to individual legal acts, primarily aimed at addressing concrete implementation challenges and making existing systems more workable in practice.

Whether additional Omnibus packages will follow beyond those already proposed and announced remains to be seen. The Commission, however, intends to continue along this path. The goal is to reduce administrative burdens for businesses by at least 25 per cent and by as much as 35 per cent for small and medium-sized enterprises (SMEs) through Omnibus packages and further simplification measures. Accordingly, in mid-February, Ursula von der Leyen emphasised to EU Heads of State or Government that the reduction of bureaucracy in the EU is far from complete.

Although many of the proposals to date may at first glance appear to have little direct relevance for social security, a closer look reveals numerous points of interaction. In particular, packages addressing sustainability, digitalisation, internal market rules and chemicals legislation contain important implications for social security systems.

What do the Omnibus initiatives mean for occupational safety and health?

The current EU reforms within the framework of the Omnibus initiatives extend far beyond individual regulatory areas. They affect several policy fields that are relevant for occupational safety and health. These include, among others, product safety, corporate sustainability reporting, developments in chemicals legislation, as well as new regulatory instruments in the internal market, for example common specifications instead of standards. Even if these topics may at first glance appear to have little in common, they share one key aspect: they influence the framework conditions for safe and healthy work. As a result, potential impacts on prevention, occupational safety and health and the activities of statutory accident insurance institutions are increasingly coming into focus.

This becomes particularly evident in the area of sustainability reporting. With the Corporate Sustainability Reporting Directive (CSRD) and the Corporate Sustainability Due Diligence Directive (CSDDD), companies are required to systematically disclose the impact of their activities on the environment and society as well as the risks along their value chains.

The specific requirements for the practical implementation of the CSRD are laid down in the European Sustainability Reporting Standards (ESRS). In practice, however, weaknesses have become apparent.

In particular, packages addressing sustainability, digitalisation, internal market rules and chemicals legislation contain important implications for social security systems.

Background on REACH

The REACH Regulation (EC) No 1907/2006 is the comprehensive framework for chemical safety that has been in force since 2007. Between 2022 and April 2026, a comprehensive revision of REACH was widely discussed but ultimately abandoned by the European Commission.

Individual indicators – for example, those relating to the reporting of occupational diseases – provide only limited reliable information on a company's actual sustainability performance. Occupational diseases are characterised by long latency periods, and corresponding data are often not sufficiently available within companies. This makes it more difficult to provide a realistic assessment at the time of reporting. Moreover, the additional administrative burden associated with data collection and reporting does not necessarily align with the European Commission's objective of reducing bureaucracy.

At the same time, a rather technical instrument is gaining importance. Under the fourth Omnibus initiative, common specifications are to be used more frequently as a regulatory instrument in cases where harmonised European standards are lacking or are not available in time. The aim is nevertheless to establish uniform requirements. Standards play an important role, particularly for occupational safety and health. They translate rather abstract legal requirements into concrete solutions for practice – for example, in the safe design of machinery, work equipment or protective equipment. Companies can rely on them in order to comply with safety requirements and minimise liability risks.

Against this background, common specifications are viewed with some ambivalence. They can serve as a kind of fallback mechanism to define uniform technical requirements and thereby provide greater clarity in practice, but they also raise questions. In particular, there is concern that established standardisation processes could be bypassed, thereby weakening procedures in which social security institutions, academia and practitioners are traditionally more strongly involved. This involvement is particularly important for occupational safety and health, as practical experience from companies feeds into the design of safety requirements.

Changes are also forthcoming in the field of chemicals. The relevant Omnibus initiative concerns, among other things, the Classification, Labelling and Packaging (CLP) Regulation as well as rules for cosmetics and fertilisers. The provisions of the CLP Regulation form a central basis for the safe handling of chemical substances in the workplace. The planned changes mainly concern product advertising and product labelling. In particular, it is envisaged to rely more strongly on digital solutions, especially for small and very small quantities, and to simplify requirements. These approaches can facilitate implementation in practice. However, careful consideration must be given to balancing relief for industry with the preservation of necessary information for occupational safety and health. It will be crucial that the existing level of protection is fully maintained. In addition, the flow of information to users must continue to be ensured. Insufficient information carries the risk of misuse and resulting accidents.

For a long time, the future of the REACH Regulation – the EU's central framework for chemical safety – was a source of uncertainty in chemicals policy. The European Commission had repeatedly announced a comprehensive revision but never followed through with concrete action. Since the end of April, it has become clear that there will be no far-reaching reform of the REACH Regulation under the von der Leyen II Commission. Instead, the responsible Commissioner for Environment, Jessika Roswall, is focusing on targeted adjustments within the existing legal framework. This approach is supported in particular by industry, as a fundamental revision of REACH could entail additional costs and administrative burdens and potentially restrict the availability of certain substances.

Commissioner Roswall plans to strengthen the enforcement of existing rules and to introduce changes via the comitology procedure – a mechanism that allows for faster amendments outside the usual legislative procedure. This makes it possible, in particular, to implement adjustments aimed at simplifying and modernising REACH – for example, in its annexes – without the formal involvement of the European Parliament. At the same time, parts of the business community are advocating for occupational safety and health requirements – such as training obligations for handling certain substances – to be removed from the REACH Regulation and instead incorporated into the relevant occupational safety and health directives.

At present, it is not yet possible to assess the concrete impact of these developments. It is clear, however, that the forthcoming decisions will shape occupational safety and health in Europe and, consequently, workplace practice.

Less bureaucracy in medical devices and in vitro diagnostics – with risks?

Simplification is also being discussed in the health sector. While there is formally no dedicated Health Omnibus, a new proposed Regulation of 16 December 2025 amending the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR) clearly follows the political guiding principle of simplification. Terms such as burden reduction, simplification, reduction of bureaucracy or cutting red tape have since shaped the debate.

This concerns a regulatory framework of great practical importance. The MDR has been in force since 2017. It was fundamentally revised following serious quality scandals, most notably the French breast implant scandal involving PIP. The aim was to ensure high safety and quality standards for medical devices. Medical devices and in vitro diagnostics cover a wide spectrum: from simple products such as contact lenses and surgical masks to blood tests and pacemakers, as well as implants and complex equipment such as MRI scanners. Before such products may be used in the EU, they must undergo clinical evaluation and certification.

This is precisely why the Regulation is now once again in focus – under the banner of reducing bureaucracy. In the political debate, there is talk of bottlenecks, costly mistakes and unnecessary bureaucracy. Manufacturers complain about lengthy certification procedures, certification bodies – the so-called Notified Bodies – about complex requirements, and Member States are concerned about the availability of certain products on the market. This can have very concrete consequences, not only for hospitals or medical practitioners that may have to wait longer for essential products or switch to alternatives but also for the provision of healthcare to insured persons.

With the current proposal for amendment, the European Commission aims to address these issues: faster certification procedures, reduced administrative burdens for manufacturers and greater predictability for Notified Bodies are intended to help ensure that the production and certification of medical devices in Europe remains attractive and that the availability of medical devices is secured. Among the measures envisaged are new classification rules, adjustments to certification requirements and specific provisions for certain product groups (such as orphan devices, breakthrough devices or well-established technologies). Simplifications are also foreseen for new technologies such as AI-based

Background on the MDR

Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) form the central European legal framework for the quality, safety and performance of medical devices and in vitro diagnostics. Their objective is to improve the safety of products placed on the market, to strengthen the requirements for clinical evaluation – particularly for high-risk products – to increase transparency through the European database EUDAMED, and to harmonise the quality and oversight of Notified Bodies across Europe. Unlike medicinal products, medical devices in the EU are not authorised by public authorities but are certified by Notified Bodies. The 2017 Regulations significantly tightened these certification requirements. As a result, many existing products must be re-evaluated and re-certified, while stricter requirements apply to new products. The MDR has applied since 26 May 2021, and the IVDR since 26 May 2022. In order to give Notified Bodies and manufacturers time to adapt, transitional periods were introduced.

medical devices. In addition, increased digitalisation of regulatory processes is intended to help accelerate procedures.

Some of these proposals are sensible. Avoiding duplicate reporting, digitalising documentation requirements or improving coordination between authorities can indeed reduce bureaucracy and make the day-to-day work of Notified Bodies and manufacturers noticeably easier without lowering the level of protection or the safety of medical devices for insured persons. This is where genuine potential for relief lies.

However, other elements that go beyond procedural simplification and weaken safety and quality requirements raise fundamental questions. This concerns, for example, the planned flexibilisation of requirements for clinical data, i.e. the question of which and how many clinical data a product must demonstrate. Changes to risk classification as well as general simplifications for certain product groups must also be critically examined. These adjustments do not only concern procedures but rather the substantive core of the MDR and IVDR. Ultimately, the issue is how thoroughly a product is tested and what level of evidence must be available before it is used for patients or in the daily work of medical professionals. This is crucial in practice. Doctors, nurses and laboratory staff must be able to rely on the safe functioning of the products they use.

Simplification must therefore not be confused with deregulation. Safety and evidence requirements are not unnecessary bureaucracy but essential protective instruments for patients and healthcare professionals. A general lowering of quality standards could shift risks – away from manufacturers and assessment bodies such as Notified Bodies, and towards patients.

Source: Own illustration DSV

It is striking that the Commission is using the current debate on reducing bureaucracy to reopen more fundamental questions. These include, for example, additional tasks for the European Medicines Agency (EMA), stricter environmental requirements for single-use products or more reporting obligations for supply shortages via EUDAMED. This shows that the discussion is not only about making rules simpler; in part, it is also about how markets are organised and how Europe can be strengthened as an economic location.

A similar development can be observed in the pharmaceutical sector. On the one hand, there is a focus on preventing supply shortages, for example through the Critical Medicines Act. On the other hand, there is also an aim to expand production in Europe and strengthen competitiveness vis-à-vis the United States and China. “Made in Europe” is to be promoted. These are legitimate objectives. However, they should be addressed through dedicated industrial policy measures – and not within legislation that primarily concerns the safety, approval and certification of products, such as the MDR.

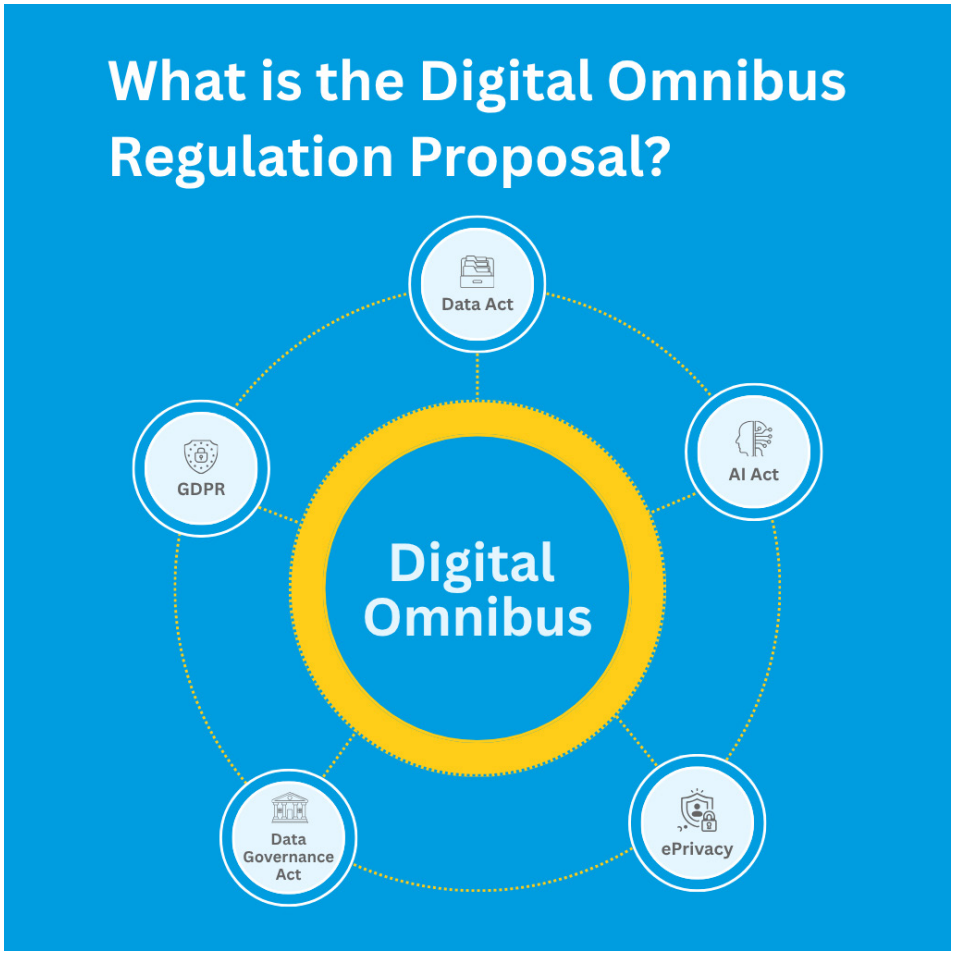
In the end, one central question remains: where does simplification genuinely help, and where does a gradual lowering of standards begin? Less bureaucracy can be meaningful – but only where procedures are streamlined without lowering the level of protection. What is crucial is that gains in efficiency do not come at the expense of patient safety, the quality of evidence and the financial sustainability of healthcare systems.

Simplification in digital policy: less bureaucracy, more clarity?

EU digital legislation has also come into focus as part of the agenda to reduce bureaucracy in autumn 2025. In this context, the European Commission has presented two proposals: a Digital Omnibus addressing data, cybersecurity and electronic identification, as well as a Digital Omnibus on AI, which provides for targeted amendments to the AI Act.

The background is that Brussels is often confronted with the criticism that, in the digital domain, too many, unclear and overlapping rules tend to hinder rather than promote innovation. Even Members of the European Parliament who were involved in drafting the relevant legislation now acknowledge that not all provisions are fit for practical implementation. This is evident, for example, in the AI Act, which was adopted in 2024 and is not yet fully applicable. In particular, it has been criticised that time pressure towards the end of the negotiations was high and that some technical requirements were adopted without sufficiently developed implementation standards. This can lead to uncertainty in practical application. At the same time, technologies such as large language models (LLMs) have developed rapidly during the legislative process, meaning that not all conceivable use cases could be taken into account.

Many experts also see a need for adjustments in data law, for example with regard to the use of personal data for research in the health sector or for the training of AI systems. Existing rules are considered only partially suitable for digital innovation. Against this background, the European Commission’s proposed Digital Omnibus responds to the frequently expressed demand to modernise existing digital legislation, reduce overlaps and create greater legal certainty.



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In practice – including in the field of social security – some of the proposed changes could indeed provide relief.

In practice – including in the field of social security – some of the proposed changes could indeed provide relief. Social security institutions are increasingly engaged in complex digitalisation processes, deploy AI systems, manage highly sensitive social data and are at the same time targets of cyberattacks. Harmonised reporting and documentation requirements, coordinated procedures for data protection impact assessments or for reporting data breaches as well as more realistic implementation timelines for the use of high-risk AI systems could facilitate practical implementation. At the same time, the proposed changes intervene in central definitions of data law and could have significant implications for the protection of social data.

It is precisely here that a fundamental tension becomes apparent, one that runs through all current simplification processes at European level: the European Commission seeks to simplify rules and reduce bureaucracy in order to promote innovation and thus strengthen Europe's competitiveness. But how far can this go without weakening European values and undermining the EU's social objectives – and thus the idea of a social Europe?

This becomes particularly clear in one central proposal within the Digital Omnibus to amend the concept of "personal data". In order to improve access to data and facilitate data processing, especially with regard to research and innovation, the European Commission has proposed to broaden the existing definition of personal data under the General Data Protection Regulation (GDPR). Until now, the rule has been that if data can theoretically be attributed to a person, they fall under the strict rules of the GDPR. In future, greater emphasis is to be placed on whether the entity processing the data can actually identify a person. The decisive factor would therefore no longer be solely whether identification is theoretically possible, but whether it appears possible for the specific entity processing the data.

For practice, this would have noticeable consequences. In particular, pseudonymised data – that is, data without direct attribution to a name – could, under certain circumstances, no longer be considered personal data. This would facilitate their processing, as many strict requirements of the GDPR would then no longer apply. At the same time, however, warnings have been raised about the risks: data protection, and in particular the protection of sensitive personal data, is a highly valued good in the EU and is enshrined in the Charter of Fundamental Rights.

Data protection authorities, including the European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS), have therefore assessed the planned extension of the definition of personal data critically. According to a joint opinion from February 2026, the Commission's proposal goes beyond a purely technical adjustment of the GDPR and beyond the existing case law of the Court of Justice of the European Union. Both authorities therefore see a risk that the proposed change could weaken the protection of personal data. In addition, this could lead to increased legal uncertainty for organisations, as it becomes less clear when data are still to be considered personal.

Thus, the central pattern of the current reforms is also evident in digital policy: simplification can help to make processes more workable. However, it becomes critical when it alters fundamental protection mechanisms. The real challenge lies in reconciling both objectives – reducing bureaucracy while maintaining a strong level of protection for rights and security.

Simplification or deregulation?

The examples from sustainability, chemicals, health and digital policy show how broad the current simplification agenda is – and how different its impacts can be. Reducing bureaucracy is, in principle, sensible. Where duplicate reporting is eliminated, procedures are digitalised or responsibilities are clarified, this facilitates work in practice. Many processes become faster and more efficient as a result.

However, this objective must not obscure the fact that some of the European Commission's proposals intervene in substantive protection standards. The debate is no longer limited to procedural issues. Can this still be described as simplification – or is it already a form of deregulation?

A look at the figures and the economic dimension also puts some expectations into perspective. The European Commission estimates that its proposed omnibus packages will reduce administrative burdens by almost 12 billion euros per year. This initially sounds like substantial savings but corresponds to only around 0.07 per cent of the EU's gross domestic product. By comparison, occupational accidents and diseases alone generate economic costs amounting to around 3 per cent of GDP.

Against this background, the question arises whether the focus is primarily on competitiveness or whether a political reassessment of existing protection standards is also taking place – not least in light of explicit calls for a Social Omnibus, which the European Commission's Directorate-General for Employment, Social Affairs and Inclusion has so far resisted. In the ongoing and forthcoming negotiations, it will therefore be crucial to allow simplification where it makes procedures more efficient without weakening the social foundations of Europe.

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