

Schreiber / Pommerening / Schoel

# New Data Act

A Practitioner's Guide



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by

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## Preface

The EU's Digital Strategy gathered pace. In recent years, a large number of new 'Digital Acts', generally EU regulations, have been submitted in draft form or have already been adopted. As a central pillar of the Data Strategy, which is part of the EU's digital agenda, the Data Act (DA) has been published in the Official Journal of the EU and marks a new chapter for the European data economy. Most of its rights and obligations have become applicable on 12.9.2025.

A radical change has been under discussion since November 2025 at the latest: The Digital Omnibus on digital acquis, the Commission's proposal for a new regulation that will change several digital acts, is intended to streamline and reduce bureaucracy. However, the Commission's proposal envisages even a significant strengthening of the Data Act: It will remain at the centre of data economy regulation and is even to be expanded to incorporate several other legal acts in the future. This clearly demonstrates the central role that this legal act will continue to play in the EU's digital regulation.

From the EU's perspective, the Data Act contains key instruments to strengthen access to and use of data across the internal market, aiming to enable fairer allocation of value and broader innovation opportunities. The focus is notably on data generated by connected products, on enhancing data accessibility for users, on clarifying data usage rights, and on facilitating data sharing between business actors and public authorities in cases of exceptional need as well as cloud switching to avoid lock-in effects and open up the market. All these elements are accompanied by efforts to foster a robust data ecosystem that underpins the EU's digital transformation. The EU Commission expects the Data Act to boost the data economy, leading to significant growth in gross domestic product.

To achieve this, the Data Act brings with it a bundle of new rights and obligations for companies, private individuals, and the public sector. It aims to nurture new business models and new forms of cooperation within its regulatory framework. Businesses, public sector bodies, and other data actors are called upon to align with the far-reaching requirements and possibilities introduced by this new EU regulation.

But will the Data Act truly fulfil its ambitious objectives? Will it actually encourage broader data access and use by individuals and businesses, foster innovation, boost the data economy and lay the foundation for a competitive and fairer EU data economy? Critical voices have emerged ever since the first drafts were made public and persist even after the adoption of the final legal text. Some concerns are valid: For example, the relationship between the Data Act and existing data protection rules – including the General Data Protection Regulation – remains only partially resolved, with both frameworks often applying in parallel. The protection of trade secrets is also inadequately regulated and could thus have the opposite effect to the goal of promoting innovation. Those subject to this law must therefore rise to the challenge of adapting to a constantly evolving and sometimes overlapping legal system and rethinking risks for their product and business model development.

We are nevertheless convinced that the Data Act can make a significant contribution to improved, fair, and competitive data usage as well as opening up cloud services and boosting interoperability. A decisive factor for success will be a sound understanding of the rights and obligations laid down in the Act. Only those who

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are aware of which rights they enjoy, the requirements the Data Act places on new business models, and what duties now apply to all market participants, will be able to confidently implement and benefit from these new instruments. Only those who are prepared for the new set of obligations can avoid administrative proceedings with possible fines and civil proceedings, thereby protecting their company from damage.

We have thus approached the project of an introductory volume to the Data Act with considerable commitment and pleasure. The present explanations are the result of many hours of analysis, discussion, and practical experience with data-driven projects and legal advice for data-driven companies. We are especially pleased to publish this work in English, enabling our reflections on the practical application of the Data Act to be received and discussed across the EU. We are convinced that the potential of the Data Act can only be realised if there is a broad, fundamental understanding of this new framework, and if we manage to discuss the critical points broadly and thus optimise them in future amendments to the regulation. It is our hope that this introductory volume provides an accessible starting point and valuable compass.

Against this backdrop, we were delighted to realise this project with the outstanding editorial team at Nomos Verlag, especially Dr. Marco Ganzhorn and Mr. Christoph Krampe. This Practitioner's Guide is part of a highly relevant, comprehensive and valued series of volumes, handbooks and commentaries on the various new legal acts arising from the EU Digital Strategy, published in partnership with Verlag C.H.Beck and Hart Publishing.

You now hold in your hands a concise introduction to the Data Act, available shortly after its key obligations have become applicable in all EU Member States on 12.9.2025, and even before the remaining obligations come into full effect on 12.9.2026. We hope this guide forms a solid foundation for establishing a first understanding of and access to this new act. This Practitioner's Guide not only addresses the articles of the Data Act itself, but also examines the surrounding challenges that may arise in the application of its instruments – including legal protection against decisions based on the Data Act. Instead of a detailed article-by-article commentary, we present its subject areas in context and in terms of their practical significance.

This volume seeks to provide guidance not only to companies seeking to unlock the Data Act for new business models, but also to companies, public authorities and other stakeholders wishing to review or develop their own data strategies in light of new competences or obligations under the Act. The same applies to all those called to shape and supervise the European data landscape going forward. Where implementation in national law still bears relevance – despite the direct applicability of EU regulations – we use Germany as an illustrative example.

We wish to thank the publishers for their unwavering support, in particular Dr. Marco Ganzhorn and Mr. Christoph Krampe. Their dedication made it possible to complete this introductory work with such quality and at an impressive pace.

Our gratitude also goes to those who assisted in organising and, above all, proofreading this volume, and without whose efforts the manuscript could not have advanced so swiftly. Special thanks go to our assistants Katharina Oschwald and Natascha Knechtel, as well as our research associates Pauline Brinke, Michèle Nickel and Benjamin Fischbach, for their precise and patient support!

*Preface*

We look forward to supplementing this Practitioner's Guide in due course with emerging developments – including the full realisation of the EU Data Strategy. While the Data Act centres on commercial and user-generated data, its interplay with other frameworks will be an exciting field of further analysis. Until then, it is our hope that this work provides helpful guidance and inspiration for all those affected by, or entitled under, the Data Act's instruments. We welcome comments, discussions and pointers to sections warranting improvement – please feel free to contact us.

Cologne, January 2026

*Kristina Schreiber*

*Patrick Pommerening*

*Philipp Schoel*

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## CHAPTER 1 THE EU DATA AND DIGITAL STRATEGY

**Bibliography:** Schmitz, ‘Digitale-Gesetze-Strategie – Agilität oder „Act“ionismus?’, ZD 2022, 189; Schreiber/Brinke, Datenschutz im EU-Gesundheitsdatenraum, PinG 2024, 251; Schreiber/Pommerening/Schoel, New Data Governance Act, A Practitioner’s Guide, 2023.

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The **EU Digital Strategy** aims to position the European Union at the forefront of the development of the digital economy in a unified single market without borders by fostering a competitive, secure, and inclusive digital surrounding. It focuses on building a **digital single market** that benefits citizens, businesses, and governments, promoting innovation, and ensuring that digital technologies contribute to a sustainable and fair society. The public and private sectors are both involved. The EU expects the digital offensive to lead to a noticeable increase in the gross domestic products of the EU Member States and more prosperity for the society.

Complementing this, the **EU Data Strategy** as part of the EU Digital Strategy seeks to create a single European data space where data can flow freely and be accessed and utilised efficiently, securely and interoperably. This strategy envisions a data-driven economy that leverages the vast amounts of data generated within the EU to drive growth, innovation, and societal progress, as well as more trust in data intermediaries and altruistic data organisations.<sup>1</sup>

With the Data Governance Act (DGA) and the Data Act (DA), the EU has adopted two key measures on the way to an EU-wide data economy:

- The **Data Governance Act** was published as Regulation (EU) 2022/868 in the Official Journal of the EU on 3.6.2022 (OJ 2022 L 152, 1). It is officially referred to as the ‘Regulation on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act)’.
- The **Data Act**, also an EU Regulation, whose official title is ‘Regulation on harmonised rules for fair access to and use of data and amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828 (Data Act)’, was published as Regulation (EU) 2023/2854 in the Official Journal of the EU (OJ L, 2023/2854) on 22.12.2023.

Together, these two legal acts form the backbone of the EU Data Strategy. In November 2025, a simplification of the Data Governance Act and Data Act is planned, initiated with the draft of a Digital Package on Simplification by the EU Commission (→ mn. 26 et seq.).

### A. EU Data Strategy

As components of the EU Commission’s **Data Strategy**, the DA and DGA are embedded in Brussels’ comprehensive Digital Strategy. In its Communication of

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<sup>1</sup> Details cf. Schreiber/Pommerening/Schoel, New Data Governance Act. A Practitioner’s Guide, Baden-Baden 2023, Ch. 3, Ch. 4.

*Chapter 1 The EU Data and Digital Strategy*

19.2.2020 on a European Data Strategy,<sup>2</sup> the Commission outlines policies and investments to help build an efficient, innovative data economy, in line with European values, fundamental rights and rules.<sup>3</sup> According to the Commission, it is important to harness the potential of the growing amount of existing data for social and economic well-being by improving **access to data** and **promoting responsible data use**.<sup>4</sup>

- 5 The Commission's vision is a **single European Data Space**, i.e. an internal market for data where both personal and non-personal data is securely handled, where companies can easily access the data they need and (re)use it in compliance with applicable laws (across industries) – regardless of where it is stored in the EU.<sup>5</sup> In addition, the EU aims to ensure free and secure data flows with **third countries**, meaning that the European data space should be accessible to data from all over the world.<sup>6</sup>
- 6 The DGA and the DA aim to create suitable framework conditions for a **data-agile European economy**.<sup>7</sup> Both Regulations are cross-sectoral measures for data access and use.<sup>8</sup>
- 7 Based on identified problematic areas in the European data economy, the policy measures and financial support planned in the Data Strategy are divided into **four pillars**:
- 8
  1. The first objective is to establish a cross-sectoral governance framework for **data access and data use** that avoids inconsistent approaches in the various sectors and Member States in the internal market.<sup>9</sup> The DA, with its data access requirements, and the DGA are the main instruments for achieving this objective. As horizontal measures, the DA and DGA address various players in the data economy across sectors.<sup>10</sup> The relationships between the stakeholders, in particular their rights and obligations, are to be standardised across the EU in order to promote the shared use of data, distribute the added value of data more fairly and increase the overall availability of data.<sup>11</sup>
- 9 A further component is the Implementing Regulation (EU) 2023/138 establishing certain high-value datasets (HVD) and the modalities of their publication and re-use, which supplements the Open Data Directive (EU) 2019/1024. The high-value datasets classified as such by the EU Commission and the Committee on Open Data and the Re-Use of Public Sector Information (see Art. 16(1) Open Data Directive) and included in the list must fulfil the conditions of Art. 14(1) subpara. 2 Open Data Directive after adoption of the implementing

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<sup>2</sup> European Commission, 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A European strategy for data' (19.2.2020), COM(2020) 66 final.

<sup>3</sup> COM(2020) 66 final, 1 et seq.

<sup>4</sup> COM(2020) 66 final, 4 et seq.

<sup>5</sup> COM(2020) 66 final, 4 et seq.; rec. 2 sent. 1 DGA.

<sup>6</sup> COM(2020) 66 final, 4 et seq.; rec. 2 sent. 1 DGA.

<sup>7</sup> COM(2020) 66 final, 12.

<sup>8</sup> COM(2020) 66 final, 12.

<sup>9</sup> COM(2020) 66 final, 12.

<sup>10</sup> COM(2020) 66 final, 12.

<sup>11</sup> COM(2020) 66 final, 13 et seq.; European Commission, 'Proposal for a Regulation of the European Parliament and of the Council on harmonised rules on fair access to and use of data (Data Act)' (23.2.2022), COM(2022) 68 final, 2 et seq.

A. EU Data Strategy

act. They must therefore be available free of charge, in machine-readable formats, via APIs and, where relevant, as a bulk download. With a view to the work in the committee, the German Federal Ministry for Economic Affairs and Climate Action had a study prepared on high-quality datasets in Germany, which was published on 10.2.2021.<sup>12</sup>

2. The second pillar of the Data Strategy aims to support **innovative, data-based business models** (especially financially) and to create the necessary infrastructural conditions for the vision of a single European Data Space.<sup>13</sup> After all, realising the potential of the European data economy requires data, cloud infrastructures and corresponding services that enable secure, sustainable, interoperable and scalable data storage and processing.<sup>14</sup>

A first practical example of such a data space is the **European Health Data Space (EHDS)**: With its Regulation on the European Health Data Space (Regulation (EU) 2025/327 – ‘EHDS Regulation’), the EU legislator has taken the first step towards creating a sector-specific common data space. The EHDS Regulation entered into force on 26.3.2025 and will be applicable from 26.3.2027 onwards. The EHDS is intended to establish a kind of platform – a decentralised data space – on and in which natural persons can post their health data and control further processing (primary data use). The EHDS Regulation is in its structure and idea based on the Data Governance Act.<sup>15</sup>

The **EHDS Regulation** is intended to create provisions for common standards and procedures, infrastructures and a governance framework within which health data can be used for primary and secondary purposes.<sup>16</sup> The Regulation is based on the right of patients to access their electronic health data in a secure environment, where they can make sovereign decisions about making this data available for further processing. This will be based on a central platform for health services – **MyHealth@EU** – set up by the Commission, and a canon of obligations for systems for electronic patient records and so-called wellness applications, which, among other things, prescribes certain technical requirements and compliance with common specifications (primary use). Research and innovation stakeholders and political decision-makers should then be able to utilise this data in a trustworthy and secure manner (secondary use).<sup>17</sup> This regulation of secondary data use will also be highly relevant in the context of the training data required for AI applications and research. This is particularly true in light of the fact that the EHDS Regulation will also regulate the use of data under data protection law and create a corresponding basis for authorisation. This is a significant difference and advantage compared to the DA and DGA, which merely leave the GDPR ‘untouched’ and thus do not solve the data protection challenges.

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<sup>12</sup> See <<https://www.bmwk.de/Redaktion/DE/Publikationen/Studien/studie-hochwertige-datensaetze-in-deutschland.html>> (last accessed: 7.1.2026).

<sup>13</sup> COM(2020) 66 final, 15 et seqq.

<sup>14</sup> COM(2020) 66 final, 20 et seq.

<sup>15</sup> COM(2022) 197 final, 4 et seq.

<sup>16</sup> Comprehensive overview by Schreiber/Brinke PinG 2024, 251 et seq.; Ruff/Schreiber EuDIR 2025, 318.

<sup>17</sup> Cf. COM(2022) 197 final, 1.