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## European regulatory framework

Research & Innovation	Industrial Policy	Connectivity	Data & Privacy	IPR	Cybersecurity	Law Enforcement	Trust & Safety	& Consumer Protection	Competition	Finance		
Digital Europe Program Regulation	Recovery and Resilience Facility Regulation	Frequency Bands Directive		Database Directive	Regulation for a Cybersecurity Act	Law Enforcement Directive	Toys Regulation		EU Merger Regulation	Common VAT system	Over	view of
Horizon Europe Regulation	InvestEU Program Regulation	Radio Spectrum Decision	GDPR	Community Design Directive	European Cybersecurity Centre	Directive: combating fraud	European Standardization Regulation	EU Accessibility Act (EEA)	Technology Transfer	Administrative cooperation (tax)	EU	
Regulation on a pilot regime distributed ledger tech. Market	Connecting Europe Facility Regulation	Broadband Cost Reduction Directive	Regulation on the free flow of non-personal data	Enforcement Directive	NIS-2 Directive	Interoperability between EU information systems in the field of borders and visas	eIDAS Regulation	Geo-blocking Regulation	Company Law Directive	Payment Services Directive 2	legislation in the digital sector	
	Regulation on Joint Undertakings under Horizon Europe	Open Internet Access Regulation	Open Data Directive	Directive on the protection of trade secrets	Information Security Regulation	Regulation on terrorist content online	Radio Equipment Directive	Regulation on cooperation for the enforcement of consumer protection laws	Market Surveillance Regulation	Digital Operational Resilience Act (DORA)	Status: August 21, 2025	
	Decision on a path to the Digital Decade	EECC	Data Governance Act (DGA)	Design Directive	Cybersecurity Regulation	Temporary CSAM Regulation	Regulation for a Single Digital Gateway	Digital Content Directive	P2B Regulation	Crypto-assets Regulation (MiCAR)		
	European Chips Act	EU top-level domain regulation	Data Act (DA)	Compulsory licensing of patents	Cyber Resilience Act (CRA)	E-evidence Regulation	General Product Safety Regulation	Directive on certain aspects concerning the sale of goods	Single Market Program	Financial Data Access Regulation	Applicable law Under	Published in the Official Journal of the EU Proposal by the
	European Critical Raw Materials Act	Roaming Regulation	European Health Data Space	Standard essential patents	Cyber Solidarity Act	Directive on combating violence against women	Machinery Regulation	Digital Services Act (DSA)	Vertical Block Exemption Regulation	Payment Services Regulation	negotiation  Planned initiative	Commission entered the legislative process  Mentioned by the Commission as
	Net Zero Industry Act	Secure Connectivity Program	Data collection for short-term rental			Digitalization of travel documents	Al Act	Political advertising regulation	Digital Markets Act (DMA)	Digital euro	Abandoned	potential legislative initiative  Negotiations failed
	STEP	Regulation RSPP 2.0	Regulation  Interoperable Europe Act				(New) Product Liability Directive	Rights to repair Directive	Regulation on distortive foreign subsidies	Regulation on combating late payment		
	EU Space Law	Digital Networks Act	ePrivacy Regulation				Al Liability Directive	e-invoicing Directive	Platform Work Directive	EU Business Wallet		
	European supercomputer capacity for Al start-ups		Digital Networks Act	Priva	ate and Confident	tial		Multimodal digital mobility services	Single Market Emergency Instrument			4

E-commerce



## Dealing with Al and EU Al Act

## Al Act - Overview

#### **Subject**

- World's first Al Act governing Al systems and Al models for general use (GPAI models)
- •"Product compliance," market surveillance and control
- → Al Act = product safety law

#### **Objective of the Al-Act**

- Safety of EU citizens
- Protection of fundamental rights
- Trust and acceptance of AI as a technology
- Promotion of innovation

#### Who is affected?

- Providers of AI systems or models
- Deployers of AI systems
- Product manufacturers who place AI systems on the market together with their product
- Extraterritorial approach

#### **Sanctions?**

- <u>Up to EUR 35 million or up to 7% of global turnover</u>
- Administrative measures (including a ban on offering Al systems)

## **Al Act: Timeline**

**April 21**, 2021

▶ EU Commission: Proposal

#### **February 2, 2025**

- ► Al literacy of personnel
- ► Prohibited Al practices

#### **August 2, 2025**

- ► General purpose Al models (GPAI)
- ► Supervisory authorities, governance, and sanctions

## August 2, 2027

- ► Embedded high-risk Al (Art. 6 in conjunction with Annex I)
- ► GPAI placed on the market before August 2, 2025

2021

2024

2025

2026

2027

030

July 12, 2024

► Publication in the Official Journal

**May 2, 2025** (at the latest)

➤ Practice guidelines are available, Art. 56(9)

#### **August 2, 2026**

► General applicability of the Al-Act

In particular

- Transparency requirements
- Non-embedded high-risk Al (Art. 6(2) in conjunction with Annex III)

#### **August 2, 2030**

► High-risk AI that is used by public authorities for their own purposes and was placed on the market before <u>August</u> 2, 2026

- Regulations already apply

#### **December 31, 2030**

▶ Al systems that are components of large-scale IT systems (Annex X) and were placed on the market or put into service before August 2, 2027.

Al systems that were placed on the market or put into service before the Al Act came into force are only subject to the Al Act if they have been *significantly* modified. Art 111 Al Act

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## Personal and territorial scope of application of the Al Act

**Personal** and **territorial**: The persons subject to the regulation are listed in Art. 2 (1) of the Al Act

- a) Providers placing on the market or putting into service AI systems or placing on the market general-purpose AI models in the Union, irrespective of whether those providers are established or located within the Union or in a third country
- b) Deployers of Al systems that have their place of establishment or are located within the Union
- c) Providers and deployers of of Al systems that have their place of establishment or are located in a third country, where the output produced by the Al system is used in the Union
- d) Importers and distributors of Al systems
- e) Product manufacturers who placing on the market or putting into service an AI system together with their product and under their own name or trademark [in the Union]\*
- Authorised representatives of providers which are not established in the Union
- **Affected persons** that are located in the Union

\*cf. Art. 1(2)(a), Art. 25(3) Al Act

## Risk-based approach of the Al Act

#### Art. 5 (1), e.g.

- · manipulative or deceptive techniques
- · biometric classification
- Inferences about the emotions of a natural person in the workplace

**Prohibited** Al practices

#### Art. 6 in conjunction with Annexes I and III, e.g.

- Employment, employee management (e.g., Al-based selection of applications), Annex III No. 4
- · Provision of services, Annex III No. 5 lit. a
- Medical devices, Annex I No. 11

For all Al systems: Building Al competence

#### Art. 4. 95

- Building Al competence
- · Voluntary codes of conduct

**High-risk Al systems** (comprehensive regulation)

## (minor regulatory requirements)

For certain Al systems: Transparency obligations

#### Commission Guidance, C(2025) 924 final:

Art. 50, e.g.

interaction with natural persons

· Generation of synthetic audio, image, video, or text content (in

· Creation or manipulation of texts

published with the aim of

· those intended for direct

(e.g., chatbots)

particular GPAI)

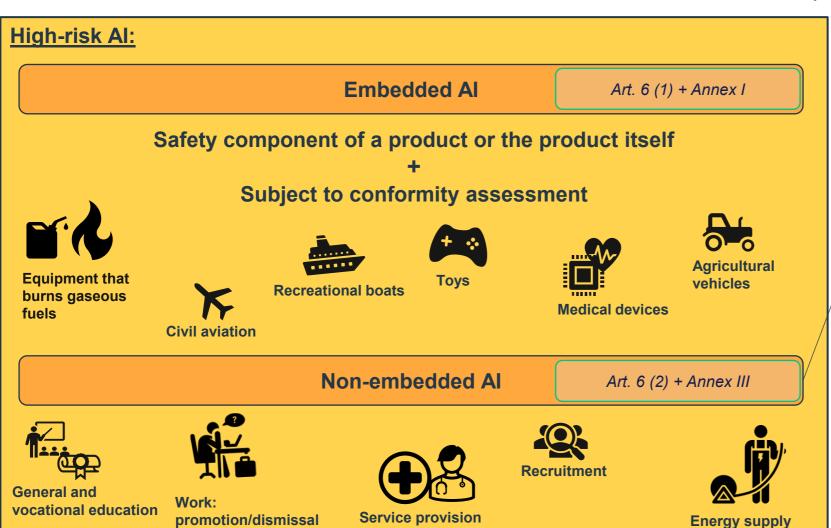
informing the public

"The vast majority of systems, even if classified as AI systems within the meaning of Article 3 No. 1 of the Al Act, are not subject to the regulatory requirements of the AI Act."

Only Articles 4 and 95 of the Al Act

## Other Al systems

## **Risk classification**



### **High-risk Al**

(comprehensive regulation)

Notwithstanding Article 6(2), the Al systems listed in Annex III shall not be considered high risk if they are intended to:

Art. 6 (3) subpara. 1

- to perform a narrow process control task;
- to improve the result of a human activity already completed;
- to identify decision patterns or deviations, and it is not intended to replace or influence the human assessment previously carried out without proper human review;
- to carry out a preparatory task for an assessment

Art. 6 (3) subpara. 2

and does not carry out profiling of natural persons

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decisions

## Requirements of the Al Act: Brief overview

#### "Normal" GPAI models:

- Technical documentation
- Compliance with copyright
- Detailed summary
- Code of conduct

#### **GPAI** models with systemic risk

- Model evaluation & amp; stress tests
- Systemic risk assessment & cybersecurity measures
- Reporting serious incidents & amp; energy efficiency reports

#### **High-risk AI systems:**

- Technical Documentation
- Quality management system
- Transparency + provision of information
- Risk management system
- Human oversight
- Cybersecurity measures
- Impact assessment for fundamental rights
- Conformity assessment procedures



# European Data Strategy (Data Act and Data Governance Act)

## **Data Governance Act (DGA)**

#### **Subject**

- Creation of an infrastructure for (voluntary) data exchange
- Removal of technical barriers

#### **Objective of the DGA**

Ensuring data availability, strengthening trust in data exchange, overcoming technical barriers

- → **Digital transformation** (through extensive data access and usage options)
- → Better management of societal challenges (e.g., climate change, mobility transition)

#### Who is affected?

- Public sector bodies
- Data intermediaries
- Data altruism organisations

#### When

Entered into force on June 23, 2022; fully applicable since **September 24, 2023** 

## **DGA: Measures**

#### **Data availability**

- Reuse of certain categories held by public bodies (e.g., confidential statistical data from the Federal Statistical Office in which a research institution has an interest)
- Data intermediation services as a key role in the data economy (e.g., through data marketplaces for data exchange between companies)
- Data altruism incentives for data donations

## Strengthening trust in data exchange

- Avoiding conflicts of interest
- Independence of pricing
- Structural separation
- Transparency, fairness & compliance
- Non-discriminatory access

## Removal of technical barriers

- Requirements for neutrality and interoperability
- Appropriate level of protection

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## Data Act (DA)

#### **Subject**

Promoting the availability and usability of data (personal and non-personal data) in the EU through:

- Data access and data use rights
- Interoperability of data and easier switching between data processing services (especially cloud services)
- Obligation to disclose data in exceptional circumstances (B2G)
- Promote Fairness in B2B and B2G Contexts

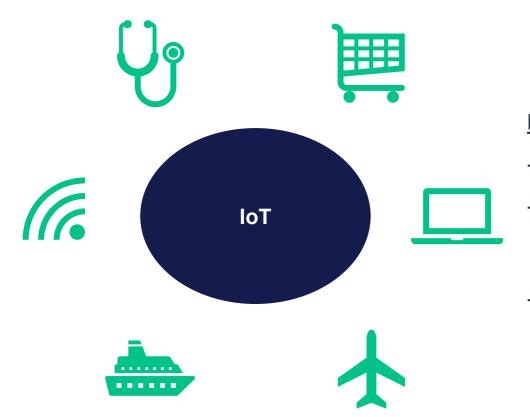
#### Who is affected?

- Data holders
- Manufacturers of connected products or related services
- Users
- Data recipients / third parties
- Data processing services

#### **When**

Entered into force on January 11, 2024; will be applicable to the greatest extent possible from September 12, 2025. **September 12, 2025** 

# Scope of application Data access: Connected products





#### **Essential characteristics of connected/loT products, Art. 2 No. 5 DA:**

- Physical item
- **Data collection:** Product collects data about its performance, use, or environment through its components or operating system ("product data," Art. 2 No. 15 DA).
- Data transmission: Product transmits product data via an electronic communication service, a physical connection, or device-internal access (e.g., terrestrial telephone networks, television cable networks, satellite networks, and near-field communication networks).

Decisive: Placing on the EU market

Excluded: Prototypes

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# Material scope Data access: Related service



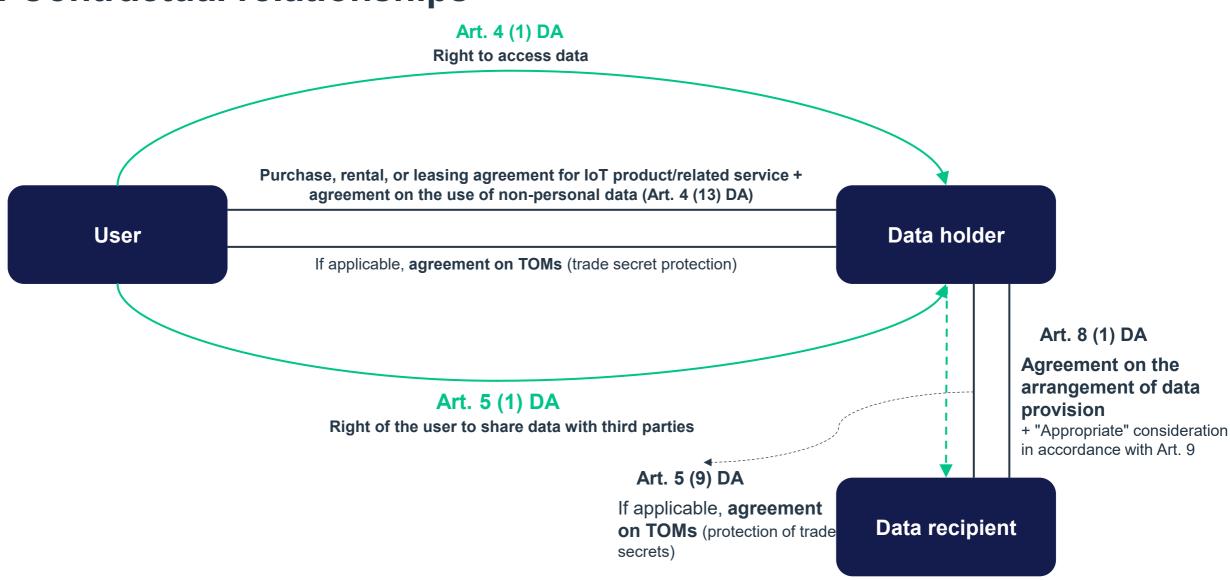
#### **Essential characteristics of connected services, Art. 2 No. 6 DA:**

- Not a physical object, but "digital" products/services (including software)
- Prerequisite: Connected product
- Mutual data exchange between the connected product and the related service.
- Related service **influences the functions**, **behavior**, **or operation** of the connected product.
- By providing the related service to the user of the connected product, the provider becomes the data owner.

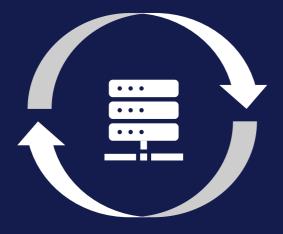
- Decisive factor: Placing on the EU market
- Excluded: Services related to connectivity and power supply, as well as aftermarket services (e.g., additional consulting, analysis, and financial services, as well as regular repair and maintenance work).

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## **DA:** Contractual relationships



## DA: Switching between data processing services



#### Fair switching between data processing services

- Breaking out of
  - lock-in effect
  - Vendor lock-in
- Promotion of fair competition

#### Requirements (providers of data processing services)

- Contract amendment (customer's right to switch)
- Removal of technical barriers to effective switching
- Duty to provide information
- Transparency
- Gradual abolition of switching fees
  - January 11, 2024 → January 12, 2027: reduced fees
  - From January 12, 2027: no fees
- Implementation of interoperability standards



# Digital Services Act Package (DSA and DMA)

## **Digital Service Act (DSA)**



#### **Subject**

Uniform horizontal rules on due diligence obligations and liability privileges for intermediary services

#### **Object**

Creation of a safe, predictable, and trustworthy online environment

→ comprehensive protection of users' fundamental rights

#### Who is affected?

<u>Providers of digital services</u> that provide consumers with goods, services, or content

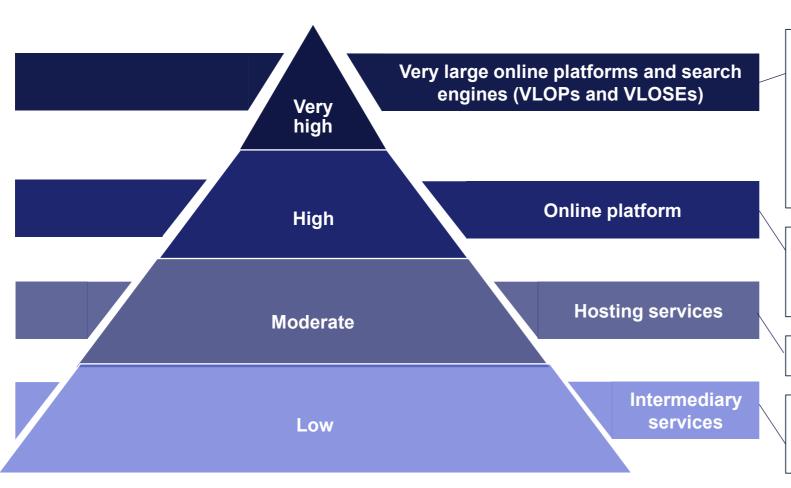
- Intermediary services
- Hosting services
- (Very large) online platforms or search engines

#### When

Entered into force on November 16, 2022; fully applicable since **February 17, 2024** 

The "Digitale-Dienste-Gesetz (DDG) implements the components of the DSA that require further elaboration in Germany.

## **DSA:** Level of due diligence



Risk of dissemination of illegal content and resulting damage particularly high

→ Reach more than 10% of the 450 million consumers in the EU

e.g. Amazon, App Store (Apple), Booking

e.g. online marketplaces, app stores, social media platforms, B2C online marketplaces

e.g. cloud services and web hosting

Provide network infrastructure: e.g., Internet service providers and domain registrars

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## **DSA: VLOPs and VLOSEs and measures**

To be designated by the Commission (see Art. 33(4) DSA)

#### **Very large online platforms (VLOPs):**

- NKL Associates s.r.o **AliExpress** (18+ service)
- **Amazon Store Pinterest**
- App Store (Apple) . Shein
- **Aylo Freesites** Snapchat (18+ service)
- Booking.com
- Temu Facebook (Meta)
- TikTok Google
- WebGroup (18+ service)

Technius (18+ service)

- Google
  - Wikipedia **Google Shopping**
- Instagram (Meta)

Available at: https://digital-

- YouTube (Google) LinkedIn
  - Zalando

strategy.ec.europa.eu/en/policies/list-designated-vlops-and-

#### Very large online search engines (VLOSEs):

- Bing
- Google Search

#### Measures taken by the DSA

**Easier removal of illegal content** (e.g., hate speech, disinformation, counterfeit products)

Prohibition of "dark patterns" and "nudging" → protection of user autonomy

**Greater transparency in advertising** 

Higher requirements for access to B2C online marketplaces

vloses

## **Digital Markets Act (DMA)**



#### **Subject**

Regulation and strengthening of digital markets by prohibiting certain practices that restrict competition

#### **Objective of the DMA**

Fair competition between digital platforms regardless of their size

- → More choice between better services at fairer prices for consumers
- → Market access for start-ups and SMEs

#### Who is affected?

So-called "gatekeepers" with certain core platform services ("CPS")

#### **When**

Entered into force on November 1, 2022; Fully applicable since **May 2, 2023** 

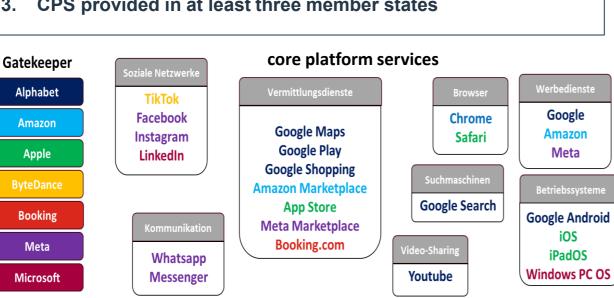
#### **Sanctions**

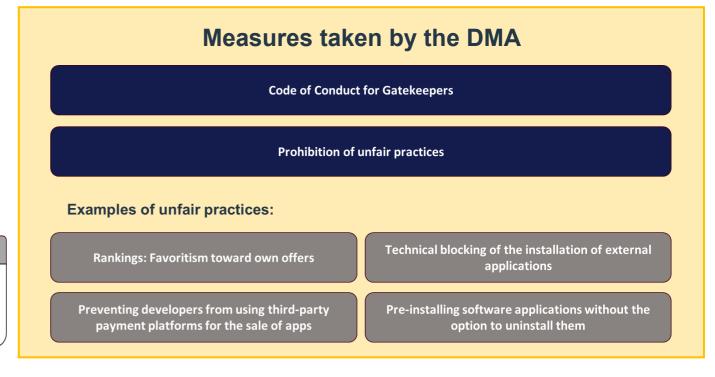
<u>Up to 10% of the gatekeeper's global turnover (up to 20% for repeated infringements)</u>

## **DMA:** Gatekeepers and measures

#### The Commission designates companies as "gatekeepers" if:

- Annual turnover exceeds EUR 7.5 billion (last three financial years) or EUR 75 billion market capitalization
- CPS has more than 45 million active users per month (including at least 10,000 commercial EU users)
- **CPS** provided in at least three member states





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# **5** EU cybersecurity (NIS-2, DORA, and CRA)

## NIS-2 and DORA at a glance

#### **NIS-2** Directive



### Digital Operational Resilience Act (DORA)



- Objective: EU-wide minimum standards for cybersecurity to make critical and important companies more resilient (Art. 1 (1) NIS-2 Directive)
- Who is affected? Public or private entities listed in Annex I ("high criticality") or II ("other critical sectors")
  - → Not only "critical infrastructure," but also, for example, digital services, food production, etc.
- **Obligations** 
  - Introduction of risk management measures (security by design, emergency plans)
  - **Reporting obligations for security incidents** (often within 24 hours)
- Geographical: in EU member states
- Time
  - Entry into force: January 16, 2023
  - Implementation deadline: by October 18, 2024
  - In Germany: NIS 2 Implementation and Cybersecurity Strengthening Act (has since been rejected by "the traffic light coalition"; to be reintroduced by the new federal cabinet in July 2025)

"Cybersecurity twins"

NIS-2: general for society and the economy

DORA: specific to the financial sector (with some higher requirements)

- Objective: To strengthen confidence in the financial markets by ensuring that they continue to function even in the event of serious cyberattacks or system failures (Art. 1 (1) DORA)
- Who is affected? Banks, insurance companies, payment service providers, stock exchanges, etc.
- **Obligations** 
  - Comprehensive IT risk management
  - Monitoring of IT service providers (cloud providers, etc.)
  - Reporting obligations in the event of IT disruptions
  - Regular resilience testing
- Geographical: in EU member states
- Time:
  - Effective date: January 16, 2023
  - Mandatory application: since January 17, 2025

Note: DORA aims to ensure that financial markets remain stable even Note: NIS-2 aims to ensure that the failure of one company does not when central IT systems come under pressure from cyberattacks or disruptions.

immediately jeopardize the supply of entire sectors of society.

## **Cyber Resilience Act (CRA)**

September 15, 2022: EU Commission proposal for a regulation on horizontal cybersecurity requirements for products with digital elements (Cyber Resilience Act)

- Introduction of security requirements for a wide range of <u>tangible and intangible products with digital elements</u>, including non-integrated software
- 11.12.2024 enactment
- 11.09.2026 reporting obligations
- 11.12.2027 enforcement

#### Scope

- Manufacturers, importers, and distributors who place a product with digital elements on the market whose intended or foreseeable use involves a logical or physical connection to a device or network
- Exceptions, e.g., for certain medical products or products for military purposes
- No SaaS
- Free and open-source software only covered for commercial use
- The terms "manufacturer" and "product with digital elements" are broadly defined

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## **CRA: Manufacturer obligations**

- Design, development, and production in accordance with Annex I CRA, e.g.
  - Products with digital elements must be designed, developed, and produced in such a way as to guarantee an <u>appropriate</u> <u>level of cybersecurity</u>
  - Products with digital elements should be delivered <u>without known exploitable vulnerabilities</u>
  - Products should be delivered with a **secure default configuration** that allows the product to be restored to its original state
- Cybersecurity Risk Assessment to minimize security risks
- Due diligence when integrating third-party components
  - Documentation requirements before the product is placed on the market
- Conformity assessment procedures (followed by CE certification + EU declaration of conformity)
- Inclusion of product information and instructions for use
- Reporting obligations, e.g., to ENISA within 24 hours of discovering vulnerabilities

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## **CRA:** Market supervisory authority and sanctions

#### **Market supervisory authority**

- Monitors the effective implementation of the Cyber Resilience Act
- Verifies the compliance of products if they pose a significant security risk

#### **Sanctions**

- For violations of the essential security requirements set out in Annex I, up to EUR 15,000,000 or 2.5% of the global turnover of the previous financial year (Art. 64(1) CRA)
- For providing false information to the market surveillance authority, up to EUR 5,000,000 or 1% of the global turnover of the previous financial year (Art. 64(4) CRA)
- In the event of other violations, up to **EUR 10,000,000** or **2%** of the global turnover of the previous financial year (Art. 64 (3) CRA)



# 6 EU Accessibility Act

## **European Accessibility Act**

#### Core idea

- EU-wide standard for accessibility of products and services
- B2C only, but B2B offerings should be fully blocked for consumers

#### Who is affected

- Manufacturers, importers, and distributors of certain products and services, e.g.
  - Products: computers, smartphones, ATMs, e-books, and ticket machines
  - Services: online shops, e-banking, electronic communication services, passenger transport tickets

#### **Object**

 People with disabilities should be able to participate independently in digital life in the European single market.

#### Scope

- Entry into force: June 28, 2019
- Implementation deadline: by June 28, 2019
- Application of the provisions since June 28, 2025 (in some cases with transition periods for products already on the market)



#### Implementation in Germany



Category	Legal basis	Scope	Exceptions		
Private providers	BFSG (applicable since 2025)	Websites, apps, e- commerce, vending machines, etc.	Micro- enterprises		
Public providers	BGG + BITV 2.0, supplemente d by BFSG	Digital services provided by public authorities	No specific exceptions mentioned		

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## **European Accessibility Act (2) – measures**

## **General functional requirements**

- Information must be perceptible, operable, understandable and robust
- Accessible interfaces: such as tactile, voice-based, or alternative operating options
- Compatibility with assistive technologies (screen readers, Braille displays, speech recognition software)
- **Accessibility statement** with information on compliance and contact details
- Reporting and documentation obligations towards supervisory authorities



- Texts, images, forms, etc. must be **machine-readable**
- Videos with subtitles and audio descriptions
- Clear and consistent user guidance, no barriers in ordering or payment processes



#### **Products**

- Operation possible via various senses (visual, acoustic, tactile)
- Clearly recognizable controls, also usable with assistive devices
- Provision of accessible instructions for use



## European digital laws – a reminder

#### Digital and data regulation guide



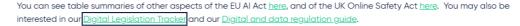


Home – Digital, data, and consumer regulation

#### Digital legislation in a page

With so much complex digital legislation coming in in the EU and UK, it can be hard to navigate even the essentials. We've produced a set of one-page overviews of key legislation at the top of the agenda for 2025, covering:

- EU Al Act
- EU Digital Services Act
- EU Data Act
- EU Data Governance Act
- EU Cyber Resilience Act
- EU NIS2 Directive
- EU Machinery Regulation
- EU Gigabit Infrastructure Act
- EU European Health Data Space proposal
- UK Online Safety Act



#### Digital legislation in a page



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Q&A



### Your contact

Axel Freiherr von dem Bussche is a specialist lawyer for information technology law in the Technology, Media & Telecoms practice group. He advises clients on national and international digital and data protection projects and is a proven expert in IT law and the GDPR.

With his many years of experience and outstanding expertise, Axel von dem Bussche expertly guides clients on both the provider and user side through complex international transactions, contract drafting, and regulatory issues. He advises corporations on their transformation to digital and global business models, supports companies in implementing AI and data protection regulations, acts as a strategic advisor to management on compliance in digitalization, and negotiates with the relevant supervisory authorities.

#### Languages

German, English, French

"Data protection specialist Axel von dem Bussche advises renowned clients on data protection issues (...). He also represents clients in proceedings at regional and national level against data protection supervisory authorities."; "He is up to date on all new developments, is very client-oriented and quickly analyzes new laws," client, Chambers Europe 2021-2024, Chambers Germany 2025

Recognized as a "Thought Leader" for data protection in Germany, Who's Who Legal 2025

Featured lawyer for data protection, Chambers Europe 2019 - 2024

Recommended for information technology and data protection "One of the best, an absolute strategist," Client, "very strong client focus, negotiating skills and assertiveness," "the expert in data protection, excellent specialist knowledge and negotiating skills," "excellent advice and specialist knowledge coupled with a strong client focus," "best lawyer in Germany for data protection litigation," client; "Very active, extremely strong," "absolute expert in the industry," "demands outstanding performance from junior staff," "pleasant and very experienced," competitor; JUVE 2015/2016- 2024/2025

Leading name for IT and digitalization, The Legal 500 2021–2025

Leading lawyer for data protection Kanzleimonitor (diruj) 2020/2021 - 2023/24

Top 100 lawyers in Germany, Kanzleimonitor (diruj) 2023/24

TOP Lawyer for Data Protection Law, WirtschaftsWoche 2019-2023

Outstanding Lawyer, Thomson Reuters 2022

Listed in the best list as a leading international lawyer for data protection and IT, Who's Who Legal 2019-2024

Highlighted as "Lawyer of the Year" 2024 and Best Lawyer for IT Law, Best Lawyers in Germany, Handelsblatt 2018 - 2024



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