



# European Data Strategies – A walk through new laws and bills: Data Act, AI Act, GDPR 2.0, NIS 2, Cyber Resilience Act, Digital Services Act, European Health Data Space - Live Webinar

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# Speakers



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# Digital Services Act

## When:

Already for VLOP/  
VLOSEs. 17 Feb  
2024 for key  
obligations for others

## Who:

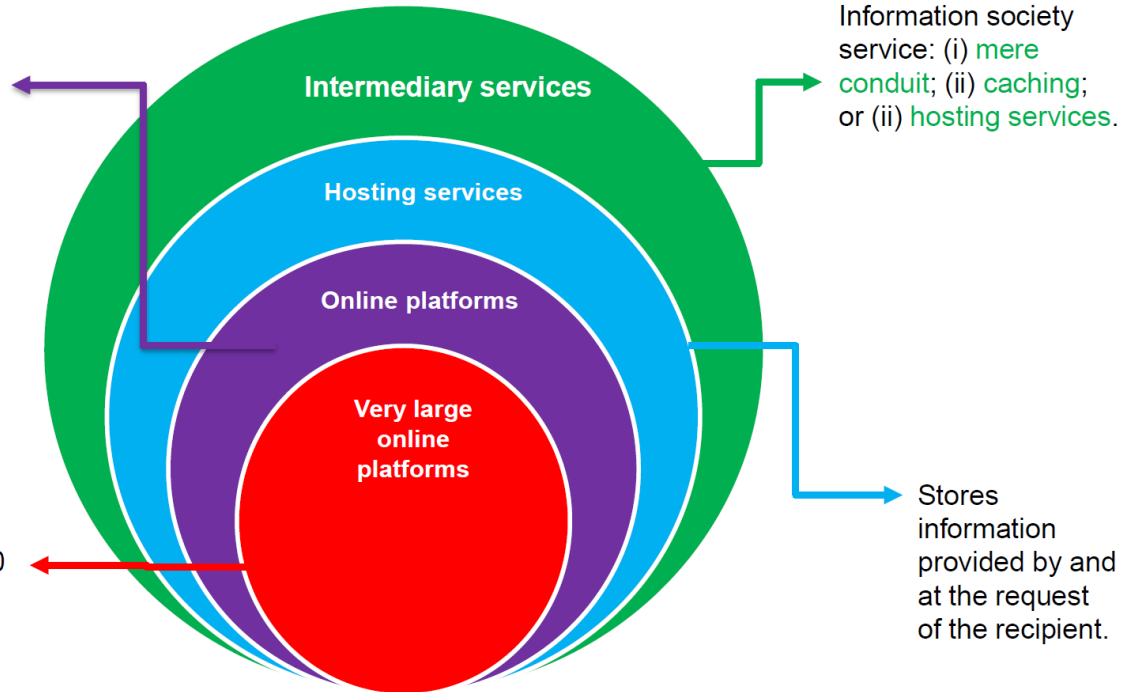
Intermediary  
Service providers

Platforms which allow  
the dissemination of  
information to the  
public.

Further subset  
includes  
**marketplaces** which  
allow traders and  
consumers to  
conclude contracts.

Platforms reaching  
more than 10% of 450  
million consumers in  
Europe.

Reed Smith



# Digital Services Act (2)

## What:



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# Data Governance Act

**When:** Entered into force 23 June 2022; Effective Date 24 September 2023

**Who:** Public and private sectors where data deemed to be a benefit to public benefit

**What:**

- Seeks to increase trust in data sharing and strengthen mechanisms to increase data availability and data reuse
- Supports the setting up of common European data spaces in health, environment, energy, agriculture, mobility/transport, finance, manufacturing, public administration and skills
- Creation of European Data Innovation Board and national Member State oversight
- New data intermediation services and voluntarily framework to make data available for altruistic purposes
- No international data transfers where there are conflicts with EU/MS law

**\*GDPR (and national law) must be complied with and prevails\***

# Data Act

**When:** Entry into Force: **11 January 2024**

Applicability: **12. September 2025** (longer transition periods for some specific provisions, **2026 to 2027**)

**Who:**

1. **Manufacturers of connected products, suppliers of related services** placed on the market in the EU (= **extraterritorial scope**) and their users
2. **Data holders** that make data available to data recipients in the EU, and such data recipients
3. **Providers of data processing services**, including cloud services, offering such services to customers in the EU
4. Participants in data spaces, vendors of applications using smart contracts and persons commercially deploying smart contracts for executing data sharing agreements
5. Member states' public sector bodies and EU institutions, agencies or bodies

# Data Act (2)

## What:

- Focuses primarily on industrial, nonpersonal data but applies also to **personal data**
- Data Holders must provide **data access** (B2B, B2C and to public sector/EU bodies)
- Multiple requirements for **Data Processing Services** (e.g. Cloud Switching)
- **Fairness test** for contractual terms in data sharing agreements unilaterally imposed on SMEs

## Key Challenges:

- Consistency with GDPR (especially where organizations process mixed datasets)
- Protection of trade secrets and intellectual property



# European Health Data Space

**When:** In Trilogue – 2026??

**Who:** “data holders” - various stakeholders including manufacturers and suppliers of Electronic Health Records (EHR) systems and wellness applications and their users and controllers and processors processing electronic health data of individuals residing in the EU

**What:**

## Primary Use

Improve  
individuals' access  
to their electronic  
health data

Interoperability of  
EHR and Digital  
Health Products  
and Services

## Secondary Use

Sharing of Health  
Data with “health  
data access  
bodies”

Access to health  
data for research  
innovation

**HealthData@EU**





# AI Act

## When:

- Adopted 9 December 2023 but not yet officially published
- Entry into Force: 20 days after publication in the Official Journal
- Applicability: 24 months after entry into force. Exceptions apply (check: Art. 87):
  - General Rules and Prohibited AI: 6 months after entry into force
  - General Purpose AI Models / Governance / Penalties: 12 months after entry into force

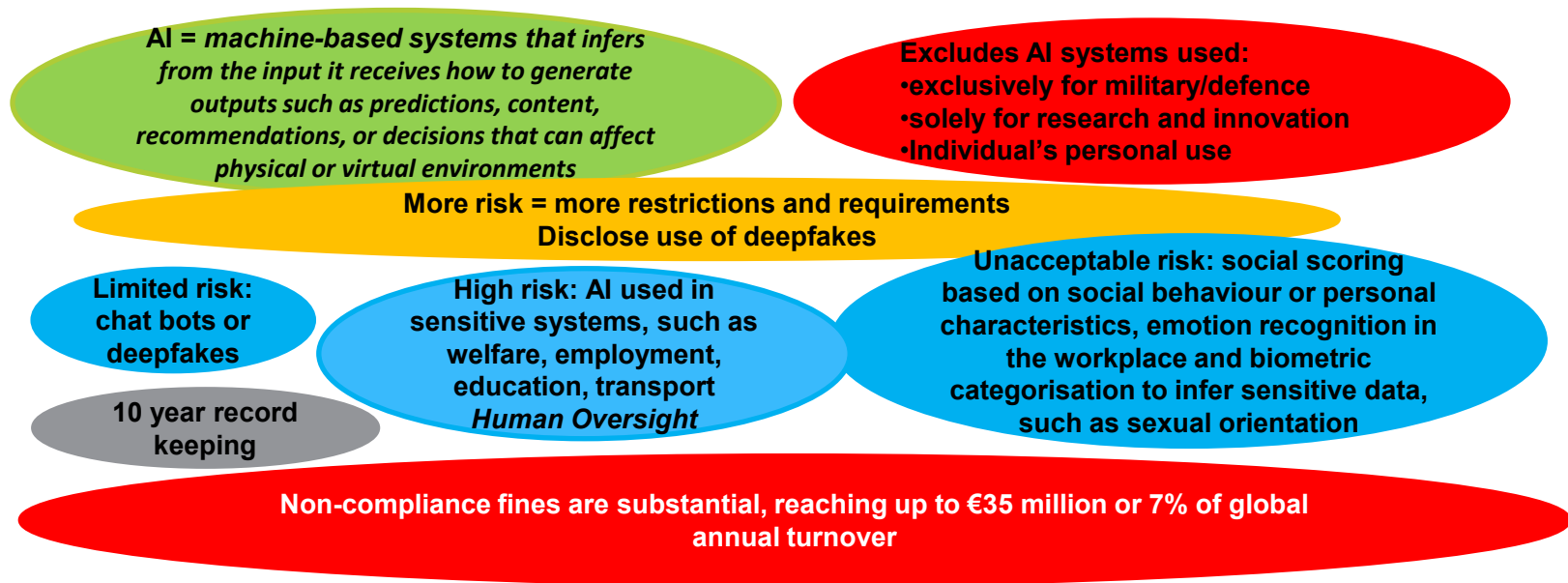
## Who:

- Providers and “deployers” of AI with an effect in the EU (extraterritorial jurisdiction)
- Manufacturers and Importers
- Users of AI



# AI Act (2) - *based on leaked consolidated draft*

## What:



# NIS 2

**When:** published on 16 January 2023 and replaces NIS1 from 18 October 2024

## Who:

- **Essential entities** (energy, transport, banking, financial market infrastructure, health sector, drinking water supply and distribution, digital infrastructure, and ICT service management)
- **Important entities** (digital providers (online marketplaces, search engines, social networking services platforms), research, food production, manufacturing of medical devices, computer, electronic and optical products, electrical equipment, machinery and equipment, transport equipment, postal and courier services, waste management, manufacture, production and distribution of chemicals)

## What:

- Requirements on the minimum cybersecurity measures (more onerous for essential entities)
- Obligation to notify incidents that have a significant impact on the provision of the services

# Legal Obligations to Notify Security Incidents

GENERAL	ESSENTIAL ENTITIES	INDUSTRY-SPECIFIC			
<div data-bbox="175 303 272 336">GDPR</div> <div data-bbox="179 350 268 441"></div> <ul data-bbox="98 456 349 718" style="list-style-type: none"><li>Any security incident involving personal data that <b><u>may cause risk</u></b> to individuals within 72 hrs of becoming aware</li><li>Existing obligation</li></ul>	<div data-bbox="484 303 562 336">NIS2</div> <div data-bbox="475 350 564 441"></div> <ul data-bbox="392 456 643 784" style="list-style-type: none"><li>Security incidents that have a <b><u>significant impact</u></b> on the provision of services within 72 hours</li><li>Legislation will be enforceable from 18 October 2024</li></ul>	<div data-bbox="784 303 852 336">CER</div> <div data-bbox="772 350 861 441"></div> <ul data-bbox="689 456 940 849" style="list-style-type: none"><li>Security incidents that <b><u>significantly disrupt</u></b> (or have a potential to disrupt) the provision of an essential service no later than 24 hours after becoming aware</li><li>Enforceable from 18 October 2024</li></ul>	<div data-bbox="1064 303 1151 336">DORA</div> <div data-bbox="1066 350 1155 441"></div> <ul data-bbox="985 456 1236 816" style="list-style-type: none"><li><b><u>Major ICT-related incidents</u></b> to the relevant competent authority (timelines to be determined, likely to be between 24-72 hrs)</li><li>Enforceable from 17 January 2025</li></ul>	<div data-bbox="1335 303 1479 336">PRA/FCA</div> <div data-bbox="1362 350 1450 441"></div> <ul data-bbox="1280 456 1532 849" style="list-style-type: none"><li>Incidents that cause <b><u>intolerable harm</u></b> to customers or the soundness, stability and resilience of the UK financial system without undue delay</li><li>Enforceable from 31 March 2025</li></ul>	<div data-bbox="1682 303 1731 336">US</div> <div data-bbox="1655 350 1744 441"></div> <ul data-bbox="1574 456 1825 816" style="list-style-type: none"><li>Rules vary from state to state</li><li>Check Reed Smith tool to find out if a legal obligations to notify applies per state per incident here: <a href="https://www.breachresponders.com">www.breachresponders.com</a></li></ul>

# Cyber Resilience Act

**When:** Political agreement between Council and Parliament end of 2023 (end of trilogue); final version to be published in the next few weeks; likely in force in 2024; new rules will apply 24 months after the law enters into force (incident reporting already after 12 months)

**Who:** Manufacturers, importers and distributors of products with digital elements (software and hardware products and components)

## What:

report	exploited vulnerabilities and incidents within 24 hours
implement	process for vulnerability handling
provide	cybersecurity risk assessments
issue	declarations of conformity
support	products for the expected lifetime (generally at least 3 years)
provide	clear and understandable instructions on product use

market surveillance	framework to enforce the rules under CRA
finances	up to 1,5% / 2,5% of annual turnover or EUR 10,000,000 / EUR 15,000,000

# GDPR 2.0

**When:** N/A

**Who:** All organizations that fall under GDPR (Art. 3 GDPR)

**What:**

- Harmonization of some aspects of the administrative procedure applied by national data protection authorities in enforcement of cross-border cases
- Official consultation by EU Commission regarding application of GDPR: Deadline for comments: Feedback period: 11 January 2024 - 08 February 2024
- Watch out for changes in local law: For example Germany: Draft of employee data protection act

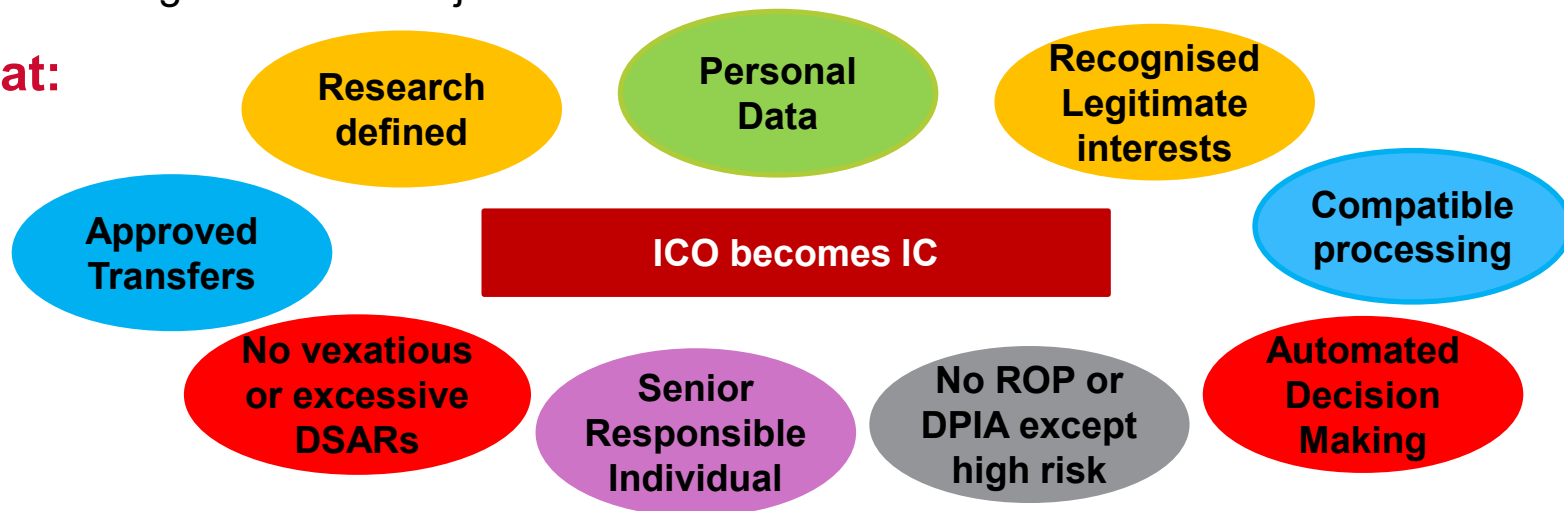


# UK Data Protection and Digital Information Bill

**When:** Likely to be passed by Parliament in 2024; currently in House of Lords

**Who:** All organisations subject to the UK GDPR and Data Protection Act 2018

**What:**



**Key Take Away:** One small step ... meant to bring more common sense to operation of the UK's version of the GDPR while not straying so much that EU adequacy is affected.

# Thank you! - Questions?





# European Data Strategies – The Acts/Drafts

**Digital Services Act:** <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32022R2065>

**Data Governance Act:** <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0868>

**Data Act:** <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0868>

**European Health Data Space:** [https://health.ec.europa.eu/document/download/756d7c59-8641-42a5-94d0-2215f97ec7e5\\_en](https://health.ec.europa.eu/document/download/756d7c59-8641-42a5-94d0-2215f97ec7e5_en)

**AI Act:** Last official version (2012): <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52021PC0206> ; Leaked final version: <https://drive.google.com/file/d/1xfN5T8VChK8fSh3wUiYtRVOKli9oIcAF/view> (Jan. 2024)

**NIS2:** <https://eur-lex.europa.eu/eli/dir/2022/2555>

**Cyber Resilience Act:** <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52022PC0454>

**UK Data Protection Bill:** <https://bills.parliament.uk/publications/53287/documents/4126>

# Further resources

## NIS2 / Cybersecurity

- NIS2 toughens up EU's cyber security obligations
- Critical Entities Resilience Directive (CER) – broader scope and more stringent obligations
- ICO expects large organisations to make financial investments to maintain their security standards
- What should data protection specialists know about the UK operational resilience requirements?

## Digital Services Act

- RS comparison table on online harms (including the DSA and OSA)

## UK Online Safety Act

- The UK Online Harms Bill becomes the Online Safety Act

## AI Act

- Leaked final version as compare: <https://drive.google.com/file/d/1xfN5T8VChK8fSh3wUiYtRVOKli9olcAF/view>

# Further resources

## GDPR 2.0

- [EDPB list with suggestions for improving the GDPR](#)
- [Information page on the GDPR initiative](#)
- [EU Commission Initiative on consultation regarding GDPR reform](#)
- [Proposal for a Regulation laying down additional procedural rules relating to the enforcement of GDPR](#)

## UK Data Protection Bill:

- <https://bills.parliament.uk/publications/53287/documents/4126>

# Further resources

## Data Act

- [Data Act & Data Governance Act – EU Data Act reaches finish line](#)
- [The Data Act enters into force](#)
- [What you need to know about the new Data Act](#)
- [Overview of the Data Act](#)

# Where we are



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