Deloitte.

EU Policy Centre Digital Playbook

November 2024

MAKING AN IMPACT THAT MATTERS since 1845

The EU Policy Centre (EUPC)

The EUPC makes Deloitte's insights and research on public policy issues and legislation available to key policy makers and to Deloitte's clients, building relationship between professionals, business leaders, and decision-makers

EU POLICY CENTRE

*Deloitte EUPC as a **trusted policy advisor***

BE AN EU LEGISLATIVE POLICY RADAR

Systematically anticipate, identify, monitor, and contribute to the **cyber** and **digital legislative developments** at the **EU policy level**, serving as a **trusted policy advisor**

PROVIDE AWARENESS TO DELOITTE CLIENTS

Proactively **identify risks and opportunities** to deliver valuable insights to clients, helping them stay ahead by anticipating **regulatory changes** and **adapting strategies** to maintain **compliance** and leverage **emerging trends**

BUILD TRUST WITH POLICY MAKERS

Develop and coordinate **relationships** with **key EU policy makers**, fostering **trust** and **credibility**

DEVELOP AND SHARE PUBLIC POLICY POSITIONS

Encourage the development of **policies** and **legislation** that **support** the **economy** and foster **inclusive growth,** ensuring that benefits extend across **industries**

The EU Policy Centre lifecycle

Among its activities, the EUPC enables a constant flow of information between our network and the institutions, forging relationships and disseminating insights useful to us and our clients

PROVISION OF DELOITTE POV

With the insights from our network and clients, **Deloitte's input forms part of the EU institutions' policy process** where the information and analysis from the market is discussed and **advice on future policy and regulation** is undertaken

COLLECTION OF INFORMATION

Deloitte participates in **stakeholder meetings** and **consultations** held by the **European Commission and Parliament**, gathering information from the various EU institutions on short-medium-long term challenges

INDUSTRY POV

At the same time, the EUPC also helps **capture responses from clients in the various geographies** as well as lessons learnt and any other marketplace evolution

COORDINATION

The EUPC then assists the various Partners in **coordinating a response** to these issues, **interpreting the regulations** and supporting in developing **standardized methodologies and solutions** which can then be utilized to inform clients in the marketplace

INSIGHT PROCESSING

The information gathered from the institutions is then **analyzed and interpreted** by the EUPC, then **socialized to the Deloitte network** through continual internal briefings, updates and newsletters

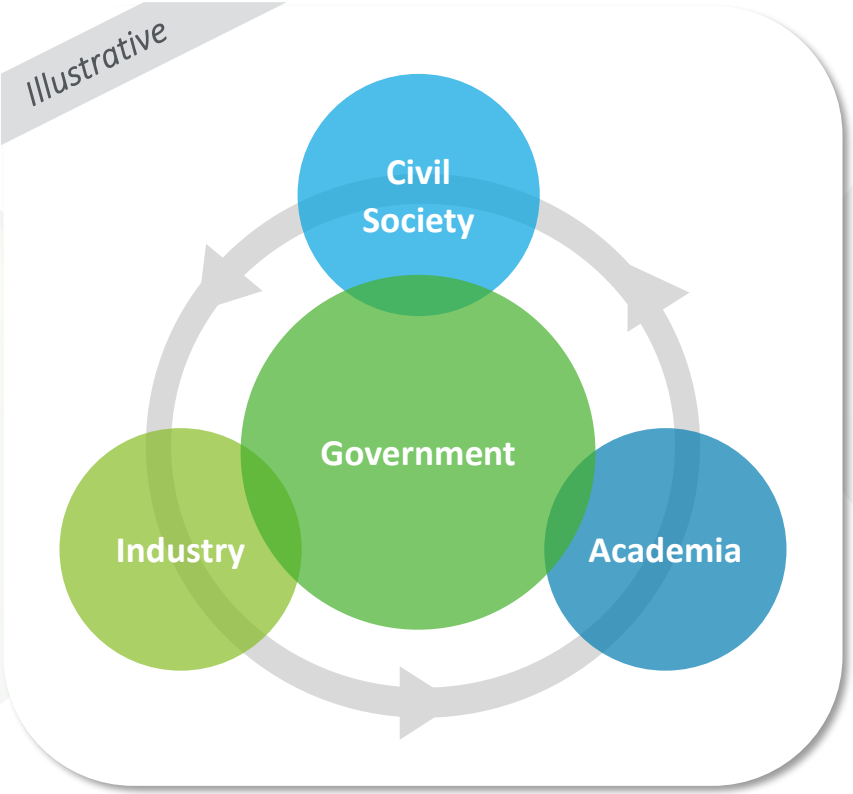
The EU Policy Centre ecosystem approach

To carry out its activities, the EUPC aims to adopt an ecosystem approach, leveraging relationships with different organizations to promote eminence and position Deloitte as a strategic advisor on key topics

EUPC Ecosystem Approach

Ecosystem based approach

Identification of **key organizations**, such as think-tanks, NGOs, universities and private technology companies in different geographic areas, and with which the EUPC can leverage **existing relationships**. Where these relationships do not yet exist, the EUPC takes steps to **create new ones** with the ultimate goal of **establishing a new ecosystem**



Promotion of eminence

Promotion of the **EUPC's eminence and reliability**, building on **Deloitte NSE's network** with the aim of achieving a **strategic advisor** position for EU policy. This is crucial, as **Cyber Diplomacy** is at the heart of the success of many EU initiatives and relies on the participation of external stakeholders

Sections of the EUPC Digital Playbook

In light of the increasing complexity of the EU digital and cyber legislative landscape, there is a compelling need to explore the new market opportunities opened by EU legislations and identify intersections and synergies among their requirements

Sections of the EUPC Digital Playbook

Technology Trends and EU Digital Strategy

From slide 10

Overview of the technological trends transforming businesses and of the EU strategy guiding legislative advancements in the digital landscape

EU Digital Legislation and Key Sectors overview

From slide 14

Overview of analyzed legislations, key sectors and use cases, and mapping of legislations' applicability to the key sectors

EU Digital Legislation Detail Cards

From slide 19

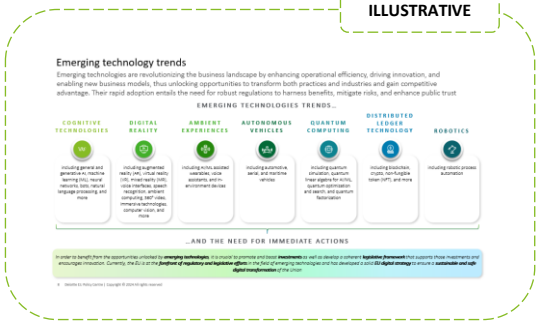
Deep-dive on the contents, targets, and regulatory stakeholders of each identified legislation, as well as intersections with other regulations

Key Sectors Use Cases

From slide 34

Deep-dive on use cases for each key sector to facilitate the understanding of the EU digital and cyber legislation's potential application

ILLUSTRATIVE



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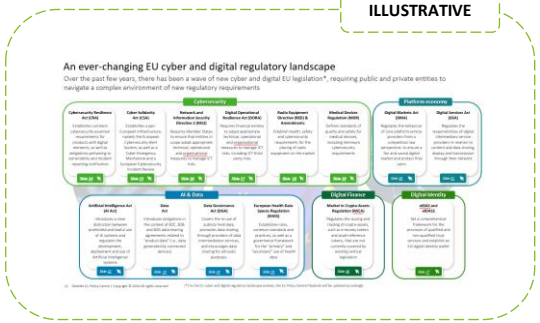

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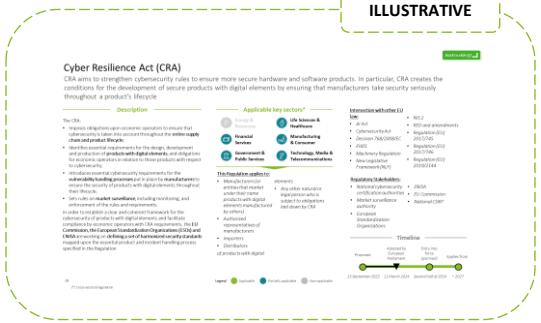

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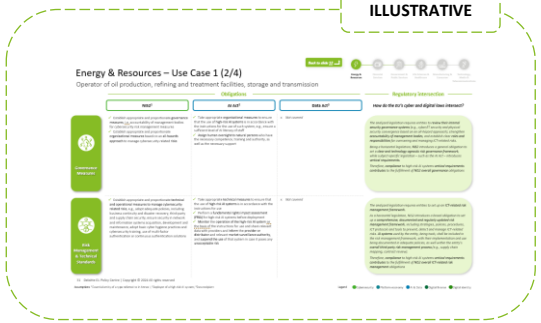


Preface to the first iteration of the EUPC Digital Playbook

Considering the broad scope of the EU cyber and digital legislation, the Playbook provides a snapshot of the current European legislative landscape and will be updated alongside regulatory changes

The EUPC Digital Playbook

Provides an overview of the **most impactful current EU digital** and **cyber legislation** and builds on foundational EU legislative initiatives from the past*

Outlines the **main requirements**** of EU digital and cyber legislation, exploring **intersections** and **synergies**

Aims to provide a **comprehensive overview** of the EU digital and cyber legislation, **without prejudice** to **national** and **local requirements**

Provides an overview of the regulations' impact on sectors even though **applicability** and **risks varies upon** the **strategies adopted** and the **services provided** at the **entity level**

Is **updated twice per year**, according to relevant developments in the EU cyber and digital legislative landscape

(*) For the scope of the EUPC Digital Playbook, the GDPR has been considered as a foundational element of the identified EU digital and cyber legislation
(**) The EUPC Digital Playbook offers a synthesis of the primary requirements of EU digital and cyber legislation; consequently, the wording used throughout the document is consistent with the wording used in the legislations

Emerging technology trends

Emerging technologies are revolutionising the business landscape by enhancing operational efficiency, driving innovation, and enabling new business models, thus unlocking opportunities to transform both practices and industries and gain competitive advantage. Their rapid adoption entails the need for robust regulations to harness benefits, mitigate risks and enhance public trust

EMERGING TECHNOLOGIES TRENDS…

COGNITIVE TECHNOLOGIES

Including general and generative AI, machine learning (ML), neural networks, bots, natural language processing and more

DIGITAL REALITY

Including augmented reality (AR), virtual reality (VR), mixed reality (MR), voice interfaces, speech recognition, ambient computing, 360° video, immersive technologies, computer vision and more

AMBIENT EXPERIENCES

Including AI/ML assisted wearables, voice assistants, and in-environment devices

AUTONOMOUS VEHICLES

Including automotive, aerial, and maritime vehicles

QUANTUM COMPUTING

Including quantum simulation, quantum linear algebra for AI/ML, quantum optimization and search, and quantum factorisation

DISTRIBUTED LEDGER TECHNOLOGY

Including blockchain, crypto, non-fungible token (NFT) and more

ROBOTICS

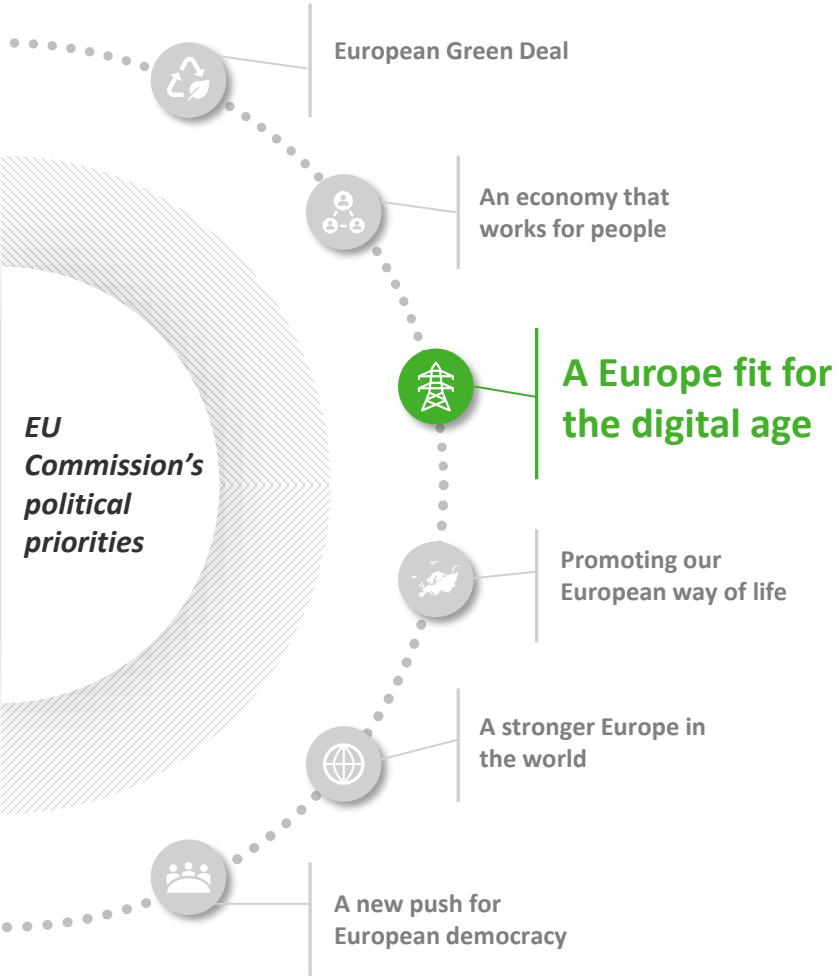
Including robotic process automation

…AND THE NEED FOR IMMEDIATE ACTIONS

*In order to benefit from the opportunities unlocked by **emerging technologies**, it is crucial to promote and boost **investments** as well as develop a coherent **legislative framework** that supports those investments and encourages innovation. Currently, the EU is at the **forefront of regulatory and legislative efforts** in the field of emerging technologies and has developed a **EU Digital Strategy** to ensure a **sustainable and safe digital transformation** of the Union*

EU Digital Strategy and priorities

The EU Digital Strategy sets up a level playing field for the adoption of new technologies, with the aim to strengthen digital sovereignty, promote a healthy and competitive internal market, protect critical infrastructures and safeguard fundamental rights of EU citizens

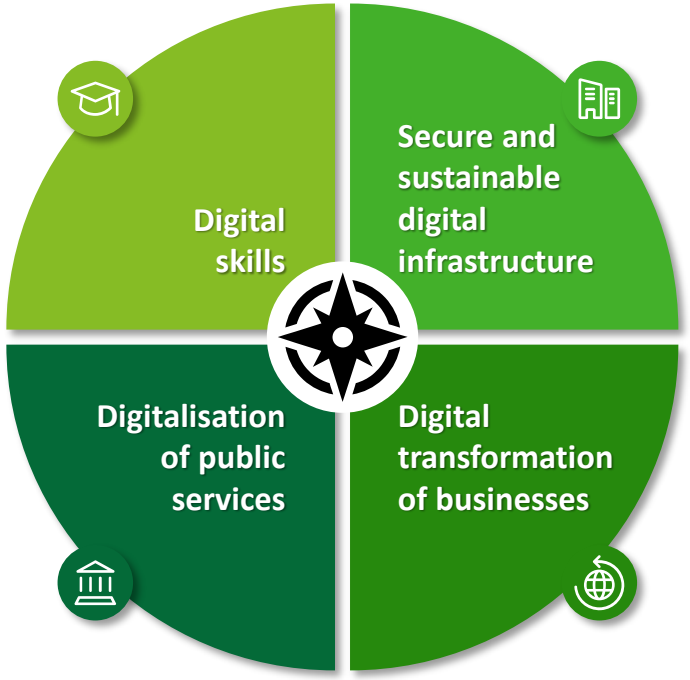


EU Digital Decade

The **EU Digital Decade*** and the **2030 Digital Compass**** constitute the overall plan to achieve a **sustainable and safe digital transformation** of the EU economy and society

2030 DIGITAL COMPASS
THE EUROPEAN WAY FOR THE DIGITAL DECADE

Cardinal points



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(*) Source: EU Commission: https://digital-strategy.ec.europa.eu/en/policies/europes-digital-decade
(**) Source: EU Commission: https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age/europes-digital-decade-digital-targets-2030_en

Progress towards EU's Digital Decade targets

On 2 July 2024, the EU Commission released the second report* on the State of the Digital Decade. This report summarizes the EU's progress towards the Digital Decade objectives and targets, highlighting the constant need for collective policy measures and investments

DIGITAL SKILLS

Policy efforts and investment to boost digital literacy and skills across the population are still needed

Based on available data, **55,6% of the EU population** has basic digital skills with the target set at 80% by 2030. Furthermore, Member States should collectively **more than double the average increase of ICT specialists** to meet labour market targets set in the Digital Decade

SECURE AND SUSTAINABLE DIGITAL INFRASTRUCTURES

The EU is still far from achieving Digital Decade targets

According to available data, the targets related to **gigabit connection** and the deployment of **highly secure and sustainable edge nodes** are still far from being achieved. Progress still needs to be made also in terms of **5G** as data on coverage does not consider the **quality of service**, which largely remains basic.

The Chips Act has triggered investments in semiconductor manufacturing and the development of the first **quantum accelerated computer** is expected by 2025

DIGITALISATION OF PUBLIC SERVICES

Digitalisation of public services has progressed in terms of access to online public services, but should be further improved, especially with regards to cross-border features

The availability of eID schemes, digital public services, and access to e-Health records **is growing**, but **notable differences remain** between countries due to varying eID adoption. There are still significant **gaps** in delivering fully user-centric, accessible, and sovereign **digital public services**

DIGITAL TRANSFORMATION OF BUSINESSES

Digitalization of businesses (i.e., SME digital identity, unicorns, and big data, cloud, and AI take-up) is still insufficient and uneven across the EU

SMEs' delay is particularly relevant with regards to the **uptake of AI**. On the other hand, data pertaining to the growth of **unicorns** is **in line with the targets** of the Digital Decade. The comparison with 2023 in terms of **Big Data** cannot be properly assessed, as the data indicator has changed and now includes the take-up of **data analytics technologies**

WHAT'S NEXT?

*Apart from developing **resilient digital infrastructures** and encouraging the spread of **technical skills** and **ethical principles** to ensure **responsible use of emerging technologies**, the need for **a coherent regulatory framework** is pivotal for the **EU** to achieve the **Digital Decade targets.** The aims of a coherent and comprehensive regulatory framework are to promote **harmonization**, ensure high standards of digital products' **safety and security**, foster **innovation**, protect **fundamental rights**, build **public trust**, unlock the full potential of the **single market**, and facilitate agile responses to **technological changes***

(*) 2024 Report on the state of the Digital Decade

An ever-changing EU cyber and digital regulatory landscape

Over the past few years, there has been a wave* of new cyber and digital EU legislation**, requiring public and private entities to navigate a complex environment of new regulatory requirements

Cybersecurity

Cybersecurity Resilience Act (CRA)

Establishes common cybersecurity essential requirements for products with digital elements, as well as obligations pertaining to vulnerability and incident reporting notification

Slide 20

Cyber Solidarity Act (CSA)

Establishes a pan-European infrastructure, namely the European Cybersecurity Alert System, as well as a Cyber Emergency Mechanism and a European Cybersecurity Incident Review

Slide 21

Network and Information Security Directive 2 (NIS2)

Requires Member States to ensure that entities in scope adopt appropriate technical, operational and organizational measures to manage ICT risks

Slide 22

Digital Operational Resilience Act (DORA)

Requires financial entities to adopt appropriate technical, operational and organizational measures to manage ICT risks, including ICT third party risks

Slide 23

Radio Equipment Directive (RED) & Amendments

Establishes health, safety and cybersecurity requirements for the placing of radio equipment on the market

Slide 24

Medical Devices Regulation (MDR)

Defines standards of quality and safety for medical devices, including minimum cybersecurity requirements

Slide 25

Platform economy

Digital Markets Act (DMA)

Regulates the behaviour of core platform service providers from a competition law perspective, to ensure a fair and sound digital market and protect final users

Slide 26

Digital Services Act (DSA)

Regulates the responsibilities of digital intermediary service providers in relation to content and data sharing, display and transmission through their network

Slide 27

AI & Data

Artificial Intelligence Act (AI Act)

Introduces a clear distinction between prohibited and lawful use of AI systems and regulates the development, deployment and use of Artificial Intelligence systems

Slide 28

Data Act

Introduces obligations in the context of B2C, B2B, and B2G data-sharing agreements related to "product data" (i.e., data generated by connected devices)

Slide 29

Data Governance Act (DGA)

Covers the re-use of publicly held data, promotes data sharing through providers of data intermediation services, and encourages data sharing for altruistic purposes

Slide 30

European Health Data Spaces Regulation (EHDS)

Establishes rules, common standards and practices, as well as a governance framework for the "primary" and "secondary" use of health data

Slide 31

Digital Finance

Market in Crypto-Assets Regulation (MiCA)

Regulates the issuing and trading of crypto-assets, such as e-money tokens and asset-reference tokens, that are not currently covered by existing vertical legislation

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Digital Identity

eIDAS and eIDAS2

Set a comprehensive framework for the provision of qualified and non-qualified trust services and establish an EU digital identity wallet

Slide 33

(*) Even though a deep dive on the GDPR is not provided in a dedicated detail card, GDPR has been considered as a foundational element of the identified EU digital and cyber legislation, and its intersections with other regulations have been considered in the key sectors' use cases

(**) As the EU cyber and digital regulatory landscape evolves, the EU Policy Centre Playbook will be updated accordingly

Key Sectors and Use Cases

To assess the impact of the EU digital and cyber legislation on public and private entities, the Playbook identifies six sectors*. For each sector, illustrative use cases have been developed to support readers understand potential applications of the identified EU legislation

Energy & Resources

This key sector includes public and private entities operating in the following industries: **electricity**, **district heating** and **cooling**, **oil**, **gas**, **hydrogen**, **drinking water**, **wastewater** and **waste management**

Financial Services

This key sector includes financial entities such as: **banking institutions** (i.e., credit institutions) and **financial market infrastructures** (i.e., operators of trading venues and central counterparties, CCPs)

Government & Public Services

This key sector includes central and local **governments, public administration** entities, and **public services** (e.g., public healthcare, transport, education)

Life Sciences & Healthcare

This key sector includes public and private entities such as: **healthcare service providers**, EU reference **laboratories**, **research and development** of **medicinal products**, manufacture of **pharmaceutical products** and **pharmaceutical preparations**

Manufacturing & Consumer

This key sector includes public and private entities operating in the following industries: **manufacturing** of **medical devices**, **computer**, **electronic** and **optical products**, **electrical equipment**, **machinery**, **motor vehicles**, trailers and semi-trailers, other **transportation equipment**, **manufacturing** of **consumer products**

Technology, Media & Telecommunications

This key sector includes public and private entities operating in the following industries: **digital infrastructure services**, **ICT service management**, **intermediary services, core platform services, qualified / non-qualified trust services, telecommunications, network connectivity**

Use Cases – Entities subject to EU digital legislation

Operator of oil production, refining and treatment facilities, storage and transmission

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Credit institution

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Insurance and reinsurance undertaking

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Public healthcare service provider (Public Hospital)

Slide 48

Manufacturer of basic pharmaceutical products and pharmaceutical preparations

Slide 52

Manufacturer of air and spacecraft and related machinery (for Defense purposes)

Slide 56

Manufacturer of motor vehicles, trailers and semitrailers

Slide 60

Provider of public electronic communications networks

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(*) Key sectors and use cases are based on Directive (EU) 2022/2555 (NIS2 Directive) Annex I and II, NACE Rev.2 Statistical classification of economic activities in the European Community, and Deloitte Industries

EU Digital legislation impact on key sectors

Below a high-level representation of the impact of the analyzed EU cyber and digital legislation against the identified sectors, acknowledging that the applicability of each legislation against entities depends on their specificities

	Cybersecurity						Platform economy		AI & Data				D. Finance	D. Identity
	CRA*	CSA	NIS2*	DORA	RED & Amendments*	MDR	DMA	DSA	AI Act*	Data Act*	DGA	EHDS	MiCA	eIDAS & eIDAS2
Energy & Resources	Partially applicable	Partially applicable	Applicable	Non-applicable	Partially applicable	Non-applicable	Non-applicable	Non-applicable	Applicable	Applicable	Non-applicable	Non-applicable	Non-applicable	Non-applicable
Financial Services**	Partially applicable	Partially applicable	Non-applicable	Applicable	Partially applicable	Non-applicable	Non-applicable	Non-applicable	Applicable	Applicable	Non-applicable	Non-applicable	Applicable	Partially applicable
Government & Public Services	Partially applicable	Applicable	Partially applicable	Non-applicable	Partially applicable	Partially applicable	Non-applicable	Non-applicable	Applicable	Applicable	Applicable	Applicable	Non-applicable	Partially applicable
Life Sciences & Healthcare	Partially applicable	Partially applicable	Partially applicable	Non-applicable	Partially applicable	Partially applicable	Non-applicable	Non-applicable	Applicable	Applicable	Non-applicable	Applicable	Non-applicable	Non-applicable
Manufacturing & Consumer	Partially applicable	Partially applicable	Partially applicable	Partially applicable	Partially applicable	Partially applicable	Non-applicable	Partially applicable	Applicable	Applicable	Non-applicable	Non-applicable	Non-applicable	Non-applicable
Technology, Media & Telecommunications	Partially applicable	Partially applicable	Partially applicable	Partially applicable	Partially applicable	Non-applicable	Applicable	Applicable	Applicable	Applicable	Applicable	Applicable	Applicable	Applicable

(*) Cross-sectoral legislation | (**) As per recital (28) of NIS2 Directive, the provisions of Regulation (EU) 2022/2554 (DORA) shall apply to the financial sector instead of the ones of NIS2 Directive

Legend: Applicable | Partially applicable | Non-applicable

Entity specificities driving the applicability of the EU digital and cyber legislation

As today's businesses are highly complex, the impact of EU digital and cyber legislation shall be evaluated from an entity perspective, taking into account the specific strategies and services of each entity, rather than focusing solely on the broader sector

Same sector, different strategies

- Sector: Consumers
- Sub-sector: Retail, Wholesale & Distribution
- 1 Company 1: Part of the clothing industry, Company 1 is expanding its presence in the **Metaverse** to promote its products and strengthen its position in the digital domain
- 2 Company 2: Part of the large organized distribution industry, Company 2 heavily relies on **IoT devices** and **robots** to speed up and improve production

Depending on their **strategies** towards the digital domain and digital products, Companies 1 and 2 might be subject to **different regulations**, and might be exposed to compliance **risks** that do not always **affect** their sector

Same sector, different services

- Sector: Technology, Media & Telecommunications (TMT)
- Sub-sector: Telecommunications, Media & Entertainment
- 1 Company 1: A network provider has a banking license to offer full **banking services** to its customers, acting as a banking institution
- 2 Company 2: A network provider focuses exclusively on core telecom business and **does not** have a banking license, providing potential financial services through partner banks

Due to the different scope of the **services** provided, Company 1 has to comply with **DORA** requirements as a **banking institution**, while Company 2 does not. Regulatory compliance and consequent risks **differ** despite the two Companies being the same type of entity

*The impact of the EU digital and cyber legislation on clients should always be considered on a **case-by-case basis***

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Cyber Resilience Act (CRA)

CRA aims to strengthen cybersecurity rules to ensure more secure hardware and software products. In particular, CRA creates the conditions for the development of secure products with digital elements by ensuring that manufacturers take security seriously throughout a product's lifecycle

Description

The CRA:

- Imposes obligations upon economic operators to ensure that cybersecurity is taken into account throughout the **entire supply chain** and **lifecycle** of products that are connected either directly or indirectly to another device or to a network, namely **products with digital elements**;
- Identifies essential requirements for the design, development and production of **products with digital elements**, and obligations for economic operators in relation to those products with respect to cybersecurity;
- Introduces essential cybersecurity requirements for the **vulnerability handling processes** put in place by **manufacturers** to ensure the security of products with digital elements throughout their lifecycle;
- Sets rules on **market surveillance**, including monitoring, and enforcement of the rules and requirements.

In order to establish a clear and coherent framework for the cybersecurity of products with digital elements and facilitate compliance by economic operators with CRA requirements, the **EU Commission,** the **European Standardization Organizations (ESOs) and ENISA** are working on **defining a set of harmonized security standards** mapped upon the essential product and incident handling process specified in the Regulation

Applicable key sectors*

- **Energy & Resources**
- **Life Sciences & Healthcare**
- **Financial Services**
- **Manufacturing & Consumer**
- **Government & Public Services**
- **Technology, Media & Telecommunications**

This Regulation applies to:

- *Manufacturers (or entities that market under their name products with digital elements manufactured by others)*
- *Authorized representatives of manufacturers*
- *Importers*
- *Distributors*

of products with digital elements

- *Any other natural or legal person who is subject to obligations laid down by CRA*

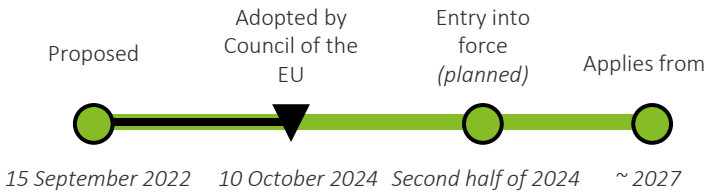
Intersection with other EU law:

- *AI Act*
- *Cybersecurity Act*
- *Decision 768/2008/EC*
- *EHDS*
- *Machinery Regulation*
- *New Legislative Framework (NLF)*
- *NIS 2*
- *RED and amendments*
- *Regulation (EU) 2017/745*
- *Regulation (EU) 2017/746*
- *Regulation (EU) 2019/2144*

Regulatory Stakeholders:

- *National cybersecurity certification authorities*
- *Market surveillance authority*
- *European Standardization Organizations*
- *ENISA*
- *EU Commission*
- *National CSIRT*

Timeline



Legend: Applicable | Partially applicable | Non-applicable

(*) Cross-sectoral legislation

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Cyber Solidarity Act (CSA)

CSA aims to strengthen common EU detection, situational awareness, and response capabilities, to gradually build an EU-level cybersecurity reserve with services from trusted private providers, and to support testing of critical entities

Description

Cyber Solidarity Act aims to **support detection** and **awareness** of **significant** or **large-scale cybersecurity threats** and **incidents**, bolster **preparedness** and protect **entities** operating in **sectors of high criticality** or **other critical sectors**, such as hospital and public utilities, strengthen solidarity at EU level, **concerted crisis management** and **response capabilities** across Member States, and contribute to ensuring a **safe** and **secure digital landscape** for citizens and businesses.

The objectives of the EU Cyber Solidarity Act will be implemented through the following actions:

- The deployment of a pan-European infrastructure of **National Cyber Hubs** (**European Cybersecurity Alert System**) to build and enhance **common detection** and **situational awareness capabilities**
- The creation of a **Cyber Emergency Mechanism** to support Member States in preparing for, responding to and immediate recovery from **significant** and **large-scale cybersecurity incidents**. Support for incident response shall also be made available to European institutions, bodies, offices and agencies of the Union (EUIBAs)
- The establishment of a **European Cybersecurity Incident Review Mechanism** to review and assess **specific significant** or **large-scale incidents**

Applicable key sectors*

- **Energy & Resources**
- **Life Sciences & Healthcare**
- **Financial Services**
- **Manufacturing & Consumer**
- **Government & Public Services**
- **Technology, Media & Telecommunications**

This Regulation applies to:

- *Users (i.e., Member States, cyber crisis management authorities, CSIRTs, CERT-EU Union institutions, bodies and agencies, Competent authorities such as Computer Security Incident Response Teams and cyber crisis management authorities of DEP-associated third countries)*
- *Trusted providers*

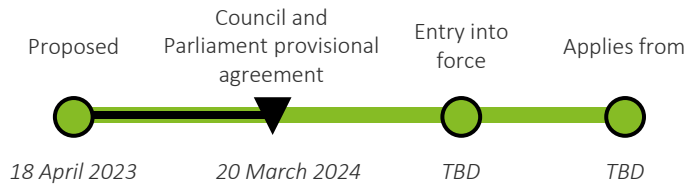
Intersection with other EU law:

- *NIS2*
- *Cybersecurity Act*
- *Regulation (EU) 2021/694 (eIDAS)*

Regulatory Stakeholders:

- *EU Commission*
- *CSIRTs/competent authority*
- *ENISA*
- *NIS Cooperation Group*

Timeline



Legend: Applicable | Partially applicable | Non-applicable

(*) Cross-sectoral legislation

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Network and Information Security Directive 2 (NIS2)

In response to the growing threats posed by digitization and the resulting increase in cyber-attacks, the EU's co-legislators have adopted new measures to ensure a high level of cybersecurity across the Union by strengthening security requirements for entities operating in "highly critical" and "critical" sectors

Description

Directive NIS2 aims to address shortcomings of the previous NIS Directive and subsequent implementation at the national level. In this regard, Directive NIS2 adopts a **clear size-cap rule** for the identification of public and private entities falling within the scope of its provision. On such basis, the Directive further distinguishes between **"essential"** and **"important" entities** depending on both the size and sector in which they operate, imposing different sets of obligations accordingly.

More specifically, to comply with NIS2 Member States:

- **shall** ensure the **management bodies of covered entities approve all the necessary measures to comply with cybersecurity risk management obligations**, oversee its implementation and can be held liable for infringements by the entities
- **shall** ensure that **entities** within the scope of the Directive **design, approve and implement detailed risk management frameworks**, namely all appropriate and proportionate technical, operational and organizational measures to manage information and ICT risks, as well as to minimise the impact of incidents
- **shall** ensure that **entities** within the scope of the Directive **notify national CSIRTs** of any incident that has a significant impact on the provision of their services
- **may** require entities within the scope of the Directive to **use certain ICT products, services and processes** that are **certified** under a scheme adopted pursuant to the Cybersecurity Act

Applicable key sectors

- **Energy & Resources**
- **Life Sciences & Healthcare**
- Financial Services
- **Manufacturing & Consumer**
- **Government & Public Services**
- **Technology, Media & Telecommunications**

This Directive applies to:

- *Public or private entities operating in "Highly critical" (Annex I) or "Critical" (Annex II) sectors (e.g., energy, transportation, health) which qualify as "medium" or "large" enterprises under Recommendation 2003/361/EC*
- *Providers of public electronic communications networks or of publicly available electronic communications services*
- *Trust service providers*
- *Top-level domain name registries and domain name system service providers*
- *Providers of domain name registration services*
- *Public administration entities of central government*
- *Public administration entities at local level (discretional)*
- *Educational institutions (discretional)*

Legend: Applicable | Partially applicable | Non-applicable

Intersection with other EU law:

- *CRA*
- *Cybersecurity Act*
- *DORA*
- *Directive 2022/2557/EU (CER)*
- *Directives 2002/58/EC, 2011/93/EU and 2013/40/EU*

Regulatory Stakeholders:

- *CSIRTs*
- *ENISA*
- *EU Commission*
- *National supervisory authorities*
- *NIS Cooperation Group*

Timeline

Proposed	Entry into force	National transposition deadline
16 December 2020	*16 January 2023*	*24 October 2024*

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Digital Operational Resilience Act (DORA)

DORA is the EU's largest digital operational resilience and cybersecurity initiative for the financial sector, and aims to transform financial players' ICT risk management processes to increase their resilience to major security incidents

Description

DORA impacts **financial players** by requiring the **transformation of governance** (top management, control functions, operational functions, business), a revision of the **operating model**, and the definition of a new **strategic risk management** approach.

Financial entities are required to build capabilities against relevant risk scenarios by identifying **critical functions/services**, mapping their **value chain** and defining **"acceptable" risk levels** to be monitored on an ongoing basis.

DORA is structured in 5 pillars:

- ICT risk management;
- ICT incident management;
- Digital operational resilience testing;
- ICT third party risk management;
- Threat intelligence and information sharing.

Top management plays a central role in defining, approving, overseeing, and being **accountable** for the implementation of a solid and documented **ICT risk management framework**, as well as a **digital operational resilience strategy** outlining how all security policies, procedures, tools and methods will be applied in practice, including the identification of the ICT risk tolerance within the overall risk appetite of the entity.

Financial Entities, other than micro-enterprises, shall assign responsibility for ICT risk management and oversight to an **independent** control function

Applicable key sectors

- Energy & Resources
- Life Sciences & Healthcare
- **Financial Services**
- **Manufacturing & Consumer**
- Government & Public Services
- **Technology, Media & Telecommunications**

This Regulation applies to:

- *Credit and payment institutions*
- *account information service providers*
- *electronic money institutions*
- *investment enterprises*
- *service providers for cryptocurrencies*
- *central securities depositories*
- *central counterparties*
- *trading venues and trade repositories*
- *alternative investment fund managers*
- *management company*
- *data communications service providers*
- *Insurance, reinsurance companies and intermediaries*
- *occupational pension institutions*
- *credit rating agencies*
- *critical benchmark index administrators*
- *crowdfunding service providers*
- *securitization data repositories third-party ICT service providers*

Legend: Applicable | Partially applicable | Non-applicable

Intersection with other EU law:

- *CRA*
- *NIS2*

Regulatory Stakeholders:

- *National supervisory authorities*
- *ECB*
- *EBA*
- *EIOPA*
- *ESMA*
- *EU Commission*

Timeline

Proposed	Entry into force	Applies from
24 September 2020	*16 January 2023*	*17 January 2025*

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Radio Equipment Directive (RED) and amendments on “common charging” solution

The Radio Equipment Directive 2014/53/EU (RED) establishes a regulatory framework for the placing on the market of radio equipment. On November 2022 and June 2023, the Commission has published two amendments to the RED, also introducing a “common charging” solution to promote the use of common chargers for mobile phones and other portable electronic devices

Description

RED ensures a single market for **radio equipment** by setting essential **requirements for safety and health, electromagnetic compatibility, and the efficient use of the radio spectrum**.

Among those, RED introduces specific requirements related to the use of **network resources, the protection of personal of users’ personal data and privacy**, as well as the integration of **anti-fraud features** (Article 3, par. 3), letters d), e) and f).

In 2022, the EU Commission adopted **Delegated Regulation (EU) 2022/30**, further specifying **cybersecurity requirements** under Art. 3(3) of RED for wireless devices. **Economic operators shall take into account such requirements while designing and Manufacturing & Consumer covered products.**

Recently, **RED has been amended** by Directive (EU) 2022/2380 which defines requirements for a “**common charging**” solution. In addition, Commission Delegated Regulation (EU) 2023/1717 updates the references to the **technical specifications** for wired charging. These requirements will apply to all handheld mobile phones, tablets, digital cameras, headphones, headsets, portable speakers, handheld videogame consoles, e-readers, earbuds, keyboards, mice, and portable navigation systems

Applicable key sectors*

- **Energy & Resources**
- **Life Sciences & Healthcare**
- **Financial Services**
- **Manufacturing & Consumer**
- **Government & Public Services**
- **Technology, Media & Telecommunications**

This Directive applies to:

- *Manufacturers (or entities that market under their name radio equipment manufactured by others)*
- *Authorised representatives of manufacturers*
- *Importers*
- *Distributors*

of radio equipment

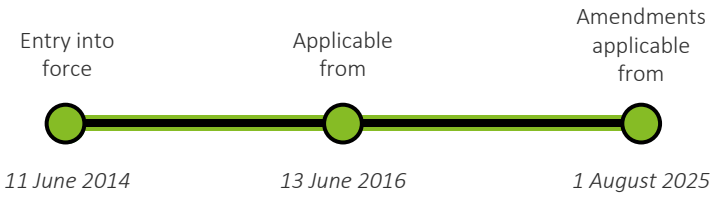
Intersection with other EU law:

- *Cyber Resilience Act*
- *Decision No 676/2002/EC*
- *Directive 98/34/EC*
- *Directive 2002/21/EC*
- *Directive 2014/35/EU*
- *Directive 2014/30/EU*
- *Regulation (EC) No 765/2008*
- *Regulation (EU) No 182/2011*
- *Regulation (EU) No 1025/2012*

Regulatory Stakeholders:

- *Market surveillance authorities*
- *Notified bodies*
- *Spectrum authorities*
- *EU Commission*
- *Telecommunication Conformity Assessment and Market Surveillance Committee*

Timeline



Legend: Applicable | Partially applicable | Non-applicable

(*) Cross-sectoral legislation

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Medical Devices Regulation (MDR) and Guidance on Cybersecurity for medical devices

The MDR aims to set high standards of quality and safety for medical devices, including minimum cybersecurity requirements for hardware, IT network characteristics and IT security measures. These requirements are thoroughly specified in the "Guidance on Cybersecurity for medical devices"

Description

Regulation EU/2017/745 (MDR) sets high **quality and safety standards for medical devices** to address common safety concerns and ensure the smooth functioning of the internal market for medical devices. The Regulation applies to "**medical devices**", namely any **instrument, apparatus, appliance, and software intended to be used for human beings for medical purposes**, such as the diagnosis, prevention, monitoring, prediction and treatment of diseases.

With regard to cybersecurity, the Regulation requires medical device manufacturers to set out **minimum requirements** for hardware, IT network characteristics, **and IT security measures**, including protection against unauthorised access, necessary for the intended use of software.

With specific regard to devices incorporating software (or software considered as devices in itself), the Regulation provides that the **software shall be developed and manufactured in accordance with the state of the art**, taking into account **SDLC principles, risk management, verification and validation**.

In addition to the general provisions of the Regulation, the cybersecurity **requirements** for medical devices **are thoroughly specified in the "Guidance on Cybersecurity for medical devices"**, drafted by the Medical Device Coordination Group established by the MDR

Applicable key sectors

- Energy & Resources
- **Life Sciences & Healthcare**
- Financial Services
- **Manufacturing & Consumer**
- **Government & Public Services**
- Technology, Media & Telecommunications

This Regulation applies to:

- *Manufacturers of medical devices*

Intersection with other EU law:

- *AI Act for horizontal AI regulation*
- *NIS2 and Cyber Resilience Act (for horizontal cybersecurity requirements)*
- *Machinery Directive ("Devices that are also machinery within the meaning of point (a) of the second paragraph of the Machinery Directive shall, where a hazard relevant under that Directive exists, also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those requirements are more specific than the general safety and performance requirements set out in Chapter II of Annex I to this Regulation.")*

Regulatory Stakeholders:

- *EU Commission*
- *Medical Device Coordination Group*
- *National competent authorities*

Timeline

Legend: Applicable | Partially applicable | Non-applicable

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Digital Markets Act (DMA)

The DMA is a competition law that aims to ensure fair competition among stakeholders operating in the digital space through obligations and prohibitions limiting the power of gatekeepers

Description

The Digital Markets Act aims to establish a **fair and more contestable digital market** by identifying **gatekeepers** (i.e., large digital platforms providing core platform services) and making them comply with a set of obligations, such as:

- **Prohibition** of **combining personal data** across different gatekeeper services and / or platforms;
- **Obligation** to allow users to **uninstall any pre-installed software** and allow the installation of third-party software;
- **Prohibition** on giving **preferential treatment** to treat their own services or products.

Non-compliance can result in **a fine** of up to 10% of global annual turnover for businesses. Providing incorrect and / or misleading information to authorities can also lead to **a fine** up to 1% of global annual turnover.

As of June 2024, the EU Commission designated as gatekeepers: **Alphabet, Amazon, Apple, ByteDance, Meta, Microsoft, and Booking**. In addition, **22 core platform services** provided by the gatekeepers have been identified. The six gatekeepers will have to ensure full compliance with the DMA obligations for each of the designated core platform services

Applicable key sectors

- Energy & Resources
- Life Sciences & Healthcare
- Financial Services
- Manufacturing & Consumer
- Government & Public Services
- **Technology, Media & Telecommunications**

This Regulation applies to:

- *Core platform service providers (e.g., online intermediation services, online search engines, online social networks, video-sharing platforms) designated as "gatekeepers" by the EU Commission in accordance with Article 3, DMA*

Intersection with other EU law:

- *Data Governance Act*
- *GDPR*

Regulatory Stakeholders:

- *EU Commission*
- *European Data Protection Supervisor*
- *European Data Protection Board*

Timeline

Proposed	Entry into force	Applies from
15 December 2020	*1 November 2022*	*2 May 2023*

Legend: Applicable | Partially applicable | Non-applicable

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Digital Services Act (DSA)

The DSA aims to create a transparent and accountable online environment by setting out rules framing the responsibilities of digital intermediary service providers with regard to the content transmitted or displayed on their network, in order to strengthen the protection of users' fundamental rights online

Description

The DSA aims to ensure user **safety online** and create an **open and competitive online platform market** by preventing harmful activities online and the spread of disinformation.

The DSA introduces a **liability regime** for "**digital intermediary service providers**". It dictates who is responsible for the content that is transferred or displayed on a communications network. Among other requirements, providers must provide **transparency in their advertising practices**, perform **risk assessments** and take responsibility for the **removal** of content after it has been flagged.

The DSA introduces different sets of obligation based on the role, size and impact on the digital ecosystem of digital intermediary service providers

Applicable key sectors

- Energy & Resources
- Life Sciences & Healthcare
- Financial Services
- **Manufacturing & Consumer**
- Government & Public Services
- **Technology, Media & Telecommunications**

This Regulation applies to:

Intermediary service providers, namely:

- *Very large online platforms (i.e., having a number of average monthly active recipients of the service equal or higher than 45 million)*
- *Online platforms*
- *Hosting service providers (including cloud and webhosting services)*
- *Intermediary service providers (including Internet access providers and Domain Name Registries)*

Intersection with other EU law:

The DSA should apply without prejudice to:

- *EU law on consumer protection (e.g., Regulations (EU) 2017/2394 and (EU) 2019/1020, Directives 2001/95/EC, 2005/29/EC , 2011/83/EU and 2013/11/EU, Council Directive 93/13/EEC, and on the protection of personal data, in particular the GDPR)*
- *Other EU law regulating the provision of information society services and intermediary services in the internal market (e.g., Directive 2010/13/EU, Reg. EU/2019/1148, EU/2019/1150, EU/2021/784, EU/2021/1232)*

Regulatory Stakeholders:

- *EU Commission*
- *European Board for Digital Services*

Timeline

Proposed	Entry into force	Applies from
15 December 2020	*15 November 2022*	*17 February 2024*

Legend: Applicable · Partially applicable · Non-applicable

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Artificial Intelligence Act (AI Act)

The AI Act aims to strengthen the safety and trustworthiness of artificial intelligence (AI) and to promote the deployment of AI systems in the EU. Its goal is to create an environment in which the opportunities of AI can be safely harnessed, while adequately safeguarding the fundamental rights of individuals and promoting a sound and competitive market

Description

The AI Act sets out rules for **developers, deployers and users of AI systems** with the aim to **drive innovation** as well as to **safeguard fundamental rights** of individuals from the risks posed by AI systems.

The Regulation distinguishes between i) prohibited AI practices, ii) high-risk AI systems, iii) general-purpose AI systems, and iv) other basic AI systems. It then sets out different obligations depending on the subjective scope and type of AI system. With regard to **high-risk AI systems**, the AI Act requires:

- Adoption of a comprehensive **AI risk management framework**, including ex-ante testing of the system as well as post-market monitoring;
- Definition of appropriate **data governance practices** in case of development and training of the AI system;
- Draft of **technical documentation** before the system is placed on the market or put into service;
- Design of **accurate, robust and (cyber)secure systems**, ensuring human oversight, and the adoption and ongoing updating of internal policies, procedures and instructions.

Failure to comply with:

- The prohibition of AI practices (Art. 5) can lead to **a fine** of up to €35M or 7% of the company's total annual worldwide turnover;
- Specific obligations imposed upon providers, importers, distributors or deployers can lead to **a fine** up to 15M or up to 3% of the company's total worldwide annual turnover

Applicable key sectors*

- **Energy & Resources**
- **Life Sciences & Healthcare**
- **Financial Services**
- **Manufacturing & Consumer**
- **Government & Public Services**
- **Technology, Media & Telecommunications**

This Regulation applies to:

- *Providers*
- *Deployers*
- *Importers and distributors*
- *Users*

of AI systems falling within the scope of the Regulation

AI Liability Directive

Proposed in September 2022, the AI Liability Directive (AILD) complements the AI Act by introducing a new liability regime that will ensure legal certainty, enhance consumer trust in AI, and assist consumers' liability claims for damage caused by AI-enabled products and services.

Legend: Applicable | Partially applicable | Non-applicable

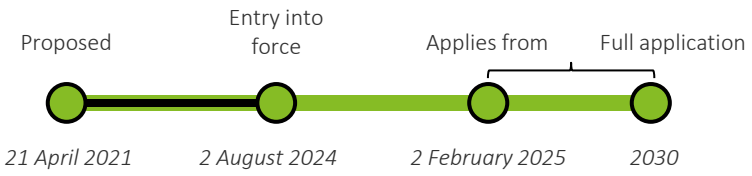
Intersection with other EU law:

- *CRA*
- *Cybersecurity Act*
- *Regulation (EU) 2019/1020 on market surveillance and compliance of products*
- *Directive 2013/36/EU on access to the activity of credit institutions*
- *New Legislative Framework (NLF)*

Regulatory Stakeholders:

- *AI Office (within the EU Commission)*
- *European Artificial Intelligence Board*
- *National competent authorities (at least one notifying authority and one market surveillance authority)*

Timeline



(*) Cross-sectoral legislation

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Data Act

The Data Act aims to improve individuals' and businesses' access to data in the EU market, especially regarding the Internet of Things (IoT) domain. The act encourages access to data while ensuring fair access and users' rights regarding data sharing, storage, and processing

Description

As a horizontal legislation, the Data Act aims to increase **legal certainty and safeguards** by introducing specific obligations in the context of **B2C, B2B, and B2G data-sharing agreements**. In particular, the Data Act **regulates** the **sharing** of **"product data"**, namely data generated by connected devices (e.g., IoT devices), for commercial purposes.

It introduces a set of measures aimed at:

- Clearly defining **acceptable uses of data** and the associated terms, while also maintaining incentives for data holders to **invest in high-quality data generation**;
- Reducing the abuse of **contractual imbalances** that impede equitable data-sharing, **to avoid unjust contractual terms** imposed by a party with a considerably stronger market position;
- Establishing **rules** that allow **public sector bodies to access and use data** held by the private sector for specific public interest purposes;
- Defining **rules** that set the **framework for customers** to effectively switch between different providers of data-processing services to facilitate interoperability and unlock the EU cloud market.
- For the purpose of supporting the negotiation of fair data-sharing agreements, the **EU Commission will develop non-binding model contract clauses**

Applicable key sectors*

- **Energy & Resources**
- **Life Sciences & Healthcare**
- **Financial Services**
- **Manufacturing & Consumer**
- **Government & Public Services**
- **Technology, Media & Telecommunications**

This Regulation applies to:

- *Data holders*
- *Data recipients*
- *Users*

Financial Data Access Regulation

Proposed in June 2023, the Financial Data Access Regulation (FIDA) is a vertical legislation derived from the Data Act and the Data Governance Act which aims to establish rights and obligations to manage customer data sharing in the financial sector

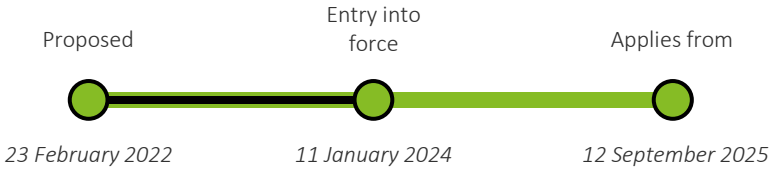
Intersection with other EU law:

- *Database Directive*
- *DGA*
- *EHDS*
- *GDPR*

Regulatory Stakeholders:

- *Data Protection Supervisor*
- *EDIB*
- *EU Commission*

Timeline



Legend: Applicable | Partially applicable | Non-applicable

(*) Cross-sectoral legislation

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Data Governance Act (DGA)

The European Strategy for Data recognises data as a critical component of the EU economy and promotes the creation of a single market where data can move safely to foster growth and digital transformation. In this context, the Data Governance Act regulates the re-use and sharing of data to safeguard citizens' trust

Description

The DGA is a cross-sectoral regulation that covers the **re-use of publicly held data** (both personal and non-personal), promotes data sharing through providers of data intermediation services (such as data marketplaces), and encourages **data sharing** for altruistic purposes. Data intermediaries will act as neutral third parties connecting data holders with data users.

The DGA sets out:

- Conditions under which **public authorities** may allow the re-use of data that are subject to the rights of others;
- A **notification and supervisory framework** for data intermediation service providers;
- A **framework for the voluntary registration** of entities collecting and processing data made available for altruistic purposes;
- A **framework for the establishment of the European Data Innovation Board** (EDIB).

Data intermediation service providers shall not use data for their own purposes and shall be free from any conflict of interest. For this purpose, the Commission has recently adopted an implementing regulation on the **design of common logos** to identify data intermediation service providers and data altruism organisations. In addition, data intermediation services providers shall not use data that they intermediate for financial purposes

Applicable key sectors

- Energy & Resources
- Life Sciences & Healthcare
- Financial Services
- Manufacturing & Consumer
- **Government & Public Services**
- **Technology, Media & Telecommunications**

This Regulation applies to:

- *Data Intermediation Services Providers (DISPs)*
- *Data Brokering Services Providers*
- *Registered Data Altruism Organisations*

Intersection with other EU law:

- *Data Act*
- *Directive 2000/31/EC*
- *Directive 2001/29/EC*
- *Directive 2004/48/EC*
- *Directive 2007/2/EC*
- *Directive 2010/40/EU*
- *Directive (EU) 2015/849*
- *Directive (EU) 2016/943*
- *Directive (EU) 2017/1132*
- *Directive (EU) 2019/790*
- *Directive (EU) 2019/1024*
- *DMA*
- *GDPR*
- *Regulation (EC) No 223/2009*
- *Regulation (EU) 2018/858*
- *Regulation (EU) 2018/1807*

Regulatory Stakeholders:

- *EU Commission*
- *European Data Innovation Board*
- *National Competent Authorities*

Timeline

Proposed	Entry into force	Applies from
25 November 2020	*23 June 2022*	*September 2023*

Legend: Applicable | Partially applicable | Non-applicable

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European Health Data Space Regulation (EHDS)

The proposed Regulation aims to establish the European Health Data Space to support individuals in taking control of their own health data, to support the use of health data to improve healthcare delivery, research, innovation and policy making, and to enable the EU to unlock the potential of a safe and secure exchange, use and reuse of health data

Description

The proposed Regulation EHDS aims to establish rules, common standards and practices, as well as a governance framework for the **"primary" and "secondary" use of health data**. The Regulation improves individuals' access to and control over their personal electronic health data, while also enabling certain data to be reused for public interest, policy support, and scientific research purposes.

More specifically, the Regulation:

- Sets rules for the placing on the market, making available on the market or put into service of **electronic health records (EHR) systems**;
- Defines rules for the **secondary use** of electronic health data;
- Establishes a **mandatory cross-border infrastructure** for **primary use** of electronic health data across the Union, as well as for **secondary use**;
- Establishes the **European Health Data Space Board** (EHDS Board) to facilitate the **cooperation and information exchange** among Member States

Applicable key sectors

- Energy & Resources
- **Life Sciences & Healthcare**
- Financial Services
- Manufacturing & Consumer
- **Government & Public Services**
- **Technology, Media & Telecommunications**

This Regulation applies to:

- *Health data holders*
- *Data users to whom electronic health data are made available by data holders*
- *Controllers and processors of electronic health data*
- *Controllers and processors established in a third country that has been connected to or is interoperable with MyHealth@EU*
- *Manufacturers and suppliers of Electronic Health Record (EHR) systems*
- *Market surveillance authorities responsible for EHR systems*
- *Health professionals, researchers and laboratories*

Intersection with other EU law:

- *AI Act*
- *CRA*
- *Data Act*
- *Data Governance Act*
- *Cross-border healthcare collaborations Directive (CBHC Directive)*
- *GDPR*
- *In Vitro Diagnostics Regulation*
- *Medical Devices Regulation*
- *NIS 2*

Regulatory Stakeholders:

- *Digital health authorities at the national level*
- *EU Commission*
- *European Health Data Space Board*

Timeline

Legend: Applicable | Partially applicable | Non-applicable

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Markets in Crypto-Assets Regulation (MiCA)

The size and scope of the crypto-asset market has grown exponentially in recent years, with little regulatory guidance in face of the rapid growth of the market and the advancement of new types of crypto assets. To this end, the EU co-legislators have adopted the Markets in Crypto-Assets Regulation (MiCA)

Description

As part of the Digital Finance Package, the MiCA lays down harmonised requirements and obligations for the offer to the public and admission to trading on **a crypto-asset trading platform**. In particular, the Regulation covers crypto-assets that are not currently regulated by existing financial services legislation, and introduces key **transparency, disclosure, authorisation and supervisory obligations** for those issuing and trading **asset-referenced tokens** (ARTs) and **e-money tokens** (EMTs).

The aims of the Regulations are threefold:

- Provide an appropriate level of **consumer protection** by imposing strict transparency obligations on issuers, offerors, traders, and providers of crypto-assets;
- Support **market integrity** and **financial stability**;
- Facilitate the use of **distributed ledger technology** in financial markets.

Offers to the public of asset-referenced tokens in the Union or applications for admission to trading of such crypto-assets should only be permitted where the competent authority has authorised the issuer of such crypto-assets and approved the relevant crypto-asset **white paper**.

Credit institutions authorised under Directive 2013/36/EU should not need any further authorisation under this Regulation to offer or seek admission to trading of asset-referenced tokens

Applicable key sectors

- Energy & Resources
- Life Sciences & Healthcare
- **Financial Services**
- Manufacturing & Consumer
- Government & Public Services
- **Technology, Media & Telecommunications**

This Regulation applies to:

- *Issuers of Asset Reference Tokens (ARTs) and e-Money Tokens (EMTs)*
- *Crypto-Asset Service Providers (CASPs)*

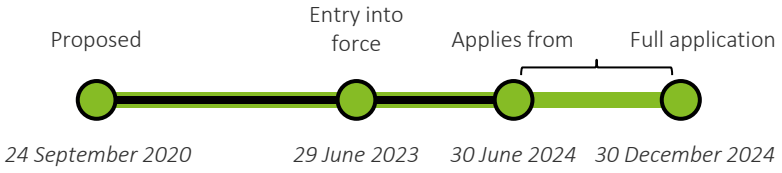
Intersection with other EU law:

- *Anti-money laundering and countering the financing of terrorism (AML/CFT) legislation*
- *Directive 2013/36/EU*
- *Directive 2024/65/EU (MiFID II)*
- *DORA*
- *Electronic Money Directive II (EMD2)*

Regulatory Stakeholders:

- *National supervisory authorities*
- *ESMA (in cooperation with EBA, EIOPA and the ECB)*
- *EU Commission*

Timeline



Legend: Applicable | Partially applicable | Non-applicable

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Regulation eIDAS and latest revision on EU digital identity framework

eIDAS, complemented by the proposed revision, sets out a comprehensive framework for the provision of qualified and non-qualified trust services, with the aim of creating a safe digital space and creating a digital wallet for EU citizens

Description

On 23 July 2014, the European Parliament and the Council of the European Union adopted the eIDAS Regulation, which establishes a clear **regulatory framework for electronic identification and trust services**. Among others, eIDAS lays down:

- A **list of trust services**, both qualified and non-qualified, including electronic signatures, seals, time stamps and authentication methods;
- Requirements for the **provision of trust services**, including, where applicable, the granting of a qualified status upon the service provider, as well as appropriate technical and organizational measures to manage security risks and ensure that the level of security is commensurate to the level of risk;
- The **obligation** of trust service providers **to notify supervisory bodies of any breach or loss that has a significant impact** on the service provided or on the personal data maintained;
- The obligation for qualified trust service providers to be **audited** at least every 24 months;
- The conditions under which Member States recognise **electronic identification means** falling under a notified electronic identification scheme of other Member States.

In order to meet the objective of making key public services available online by 2030, the EU Commission recently proposed a **revision of eIDAS** in 2021 to set the baseline for electronic attestation of attributes and an **EU digital identity wallet**

Applicable key sectors

- Energy & Resources
- Life Sciences & Healthcare
- **Financial Services**
- Manufacturing & Consumer
- **Government & Public Services**
- **Technology, Media & Telecommunications**

This Regulation applies to:

- *Trust service providers*
- *Qualified trust service providers*

Intersection with other EU law:

- GDPR

Regulatory Stakeholders:

- *National supervisory authorities*
- *National conformity assessment bodies*
- *ENISA*
- *EU Commission*

Timeline

eIDAS adopted	Revision proposed	Entry into force
July 2014	*3 June 2021*	*20 May 2024*

Legend: Applicable | Partially applicable | Non-applicable

Key sectors Use Cases: categories and assumptions

In order to enhance the understanding of the legislative requirements and highlight intersections, obligations targeting stakeholders across different sectors have been clustered into six categories for each use case and assumptions have been developed

Categories used to cluster legislative requirements

The EU cyber and digital legislations requirements have been categorized into seven categories to provide an overview and streamline enforcement actions

- Governance Measures
- Risk Management & Technical Standards
- Vulnerability Management
- Incident Management
- ICT Security Compliance & Certification
- Data Governance & Management

Assumptions

Each legislation imposes specific requirements on companies according to different roles (e.g., manufacturer, importer, distributor). Thus, an assumption about the specific role has been made for each use case. Due to the complexity and variability of legal contexts, these use cases should not be seen as comprehensive or universally applicable:

ILLUSTRATIVE

NIS2[1]	AI Act[2]	Data Act[3]

Assumptions [1] Essential entity of a type referred to in Annex I; [2]Deployer of a high-risk AI system; [3]Data recipient

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Energy & Resources – Use Case 1 (1/4)

The Energy & Resources use case 1 provides an illustrative snapshot of how an Operator of oil production, refining and treatment facilities, storage and transmission is impacted by the identified EU digital and cyber legislation and is based on a set of assumptions that may not account for all possible scenarios

Sector

Energy & Resources: This sector includes public and private entities operating in the following industries: electricity, district heating and cooling, oil, gas, hydrogen, drinking water, wastewater and waste management

Identification of an entity within the sector

Entity

Operator of oil production, refining and treatment facilities, storage and transmission

Definition of the assumptions to build an illustrative use case

Assumptions

Since each legislation imposes specific requirements on entities based on their roles, it is assumed that the Operator of oil production, refining and treatment facilities, storage and transmission, under the selected legislation, acts as:

NIS2	AI Act	Data Act
Essential entity	Deployer of a high-risk AI system	Data recipient
An entity referred to in Annex I "Sectors of High Criticality," which exceeds the ceilings for medium-sized enterprises.	Any individual, organization, government body, agency, or entity using an AI system under its control, unless the AI system is being used for personal, non-professional purposes.	Any individual or organization acting for purposes related to their trade, business, craft, or profession, excluding the user of a connected product or service, to whom the data holder provides access to data. This may include a third party.

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Energy & Resources – Use Case 1 (2/4)

Operator of oil production, refining and treatment facilities, storage and transmission

Obligations

	NIS2[1]	AI Act[2]	Data Act[3]
Governance Measures	✓ Establish appropriate and proportionate **governance measures**, i.e. accountability of management bodies for cybersecurity risk management measures ✓ Establish appropriate and proportionate **organizational measures** based on an **all-hazards approach** to manage cybersecurity related **risks**	✓ Take appropriate **organizational measures** to ensure that the use of **high-risk AI systems** is in accordance with the instructions for the use of such system, e.g., ensure a sufficient level of AI literacy of staff ✓ **Assign human oversight to natural persons** who have the necessary competence, training and authority, as well as the necessary support	x *Not covered*
Risk Management & Technical Standards	✓ Establish appropriate and proportionate **technical and operational measures to manage cybersecurity related risks**, e.g., adopt adequate policies, including business continuity and disaster recovery, third-party and supply chain security, ensure security in network and information systems acquisition, development and maintenance, adopt basic cyber hygiene practices and cybersecurity training, use of multi-factor authentication or continuous authentication solutions	✓ Take appropriate **technical measures** to ensure that the use of **high-risk AI systems** is in accordance with the instructions for use ✓ Perform a **fundamental rights impact assessment (FRIA)** for high-risk AI systems before deployment ✓ **Monitor** the **operation of the high-risk AI system** on the basis of the instructions for use and share relevant data with providers and **inform** the **provider or distributor** and relevant **market surveillance authority**, and **suspend the use** of that system in case it poses any **unacceptable risk**	x *Not covered*

Regulatory intersection

How do the EU's cyber and digital laws intersect?

*The analyzed legislation requires entities to **review their internal security governance systems** (e.g., cyber/IT security and physical security convergence based on an all-hazard approach), strengthen **accountability of management bodies**, and establish clear **roles and responsibilities** for overseeing and managing ICT-related risks.*

*Being a horizontal legislation, **NIS2** introduces a general obligation to set a **clear and technology-agnostic risk governance framework**, while subject-specific legislation – such as the AI Act – introduces **vertical requirements**.*

*Therefore, **compliance** to high-risk AI systems **vertical requirements contributes** to the fulfillment of **NIS2 overall governance** obligations*

*The analyzed legislation requires entities to set up an **ICT-related risk management framework.***

*As a horizontal legislation, NIS2 introduces a broad obligation to set up a **comprehensive, documented and regularly updated risk management framework**, including strategies, policies, procedures, ICT protocols and tools to prevent, detect and manage ICT-related risks. **AI systems** used by the entity, being tools, shall be included in the risk management framework, with their implementation and use being documented in adequate policies, as well within the entity's **overall third-party risk management process** (e.g., supply chain mapping, contract review).*

*Therefore, **compliance** to high-risk AI systems **vertical requirements contributes** to the fulfillment of **NIS2 overall ICT-related risk management** obligations*

The use case is based on a set of assumptions, as per slide 36, that may not account for all possible scenarios: [1] Essential entity of a type referred to in Annex I; [2]Deployer of a high-risk AI system; [3]Data recipient

Legend: Cybersecurity | Platform economy | AI & Data | Digital finance | Digital identity

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Energy & Resources – Use Case 1 (3/4)

Operator of oil production, refining and treatment facilities, storage and transmission

Obligations

	NIS2[1]	AI Act[2]	Data Act[3]
Vulnerability Management	✓ Establish appropriate and proportionate **technical** and **operational measures** to **manage vulnerabilities** and **report** them to the **national CSIRT** an, where needed, to **service recipients** ✓ Take into account **vulnerabilities** specific to **direct suppliers** and **service providers** and the overall **quality of their products** and cybersecurity **practices**	x *Not covered*	x *Not covered*
Incident Management	✓ Establish appropriate and proportionate **technical** and **operational** measures for **incident handling** ✓ Establish **business continuity** measures, such as backup management and **disaster recovery**, and **crisis management** ✓ Notify to **national CSIRT**, or **competent authority**, any **incident** that has a **significant impact** on the provision of the operator's services	✓ **Monitor** the **operation of the high-risk AI system** on the basis of the instructions for use and share relevant data with providers within their post-market monitoring activities, including data regarding any **discovered serious incident** ✓ **Inform** first the **provider**, and then the **importer** or **distributor** and the relevant **market surveillance authorities** in case of a **serious incident** as defined in Article 3(49)	x *Not covered*

Regulatory intersection

How do the EU's cyber and digital laws intersect?

*The analyzed legislation requires entities to implement **appropriate measures** and processes to **manage ICT system vulnerabilities**, such as **periodic vulnerability assessment and penetration testing**, as well as to **record and mitigate** such vulnerabilities either directly or with the involvement of ICT providers.*

*With regard to **AI systems**, **deployers cannot directly test the infrastructure** of the AI system. It is likely that they will oversee the overall security of the AI system through their **overall third-party risk management framework** (e.g., reviewing supply chains and negotiating specific contractual clauses).*

*The analyzed legislation requires entities to set up appropriate measures for **ICT incident reporting** and **handling**.*

*While NIS2 outlines measures for the notification of **ICT significant incidents** to national CSIRTs, or competent authorities, the AI Act outlines measures for the notification of **serious incidents** to **market surveillance authorities.***

*The legislation aims to **simplify** and **streamline** reporting procedures by encouraging the establishment of national **single-entry points** for the fulfillment of reporting requirements. Currently, the **AI Act** falls **outside such requirements** and envisages notification procedures towards **market surveillance authorities.** However, such authorities are **encouraged to correspond to single entry points.***

The use case is based on a set of assumptions, as per slide 36, that may not account for all possible scenarios: [1] Essential entity of a type referred to in Annex I; [2]Deployer of a high-risk AI system; [3]Data recipient

Legend: Cybersecurity | Platform economy | AI & Data | Digital finance | Digital identity

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Energy & Resources – Use Case 1 (4/4)

Operator of oil production, refining and treatment facilities, storage and transmission

Obligations

	NIS2[1]	AI Act[2]	Data Act[3]
ICT Security Compliance & Certification	✓ ***May*** be required to use **IT/OT products**, **services** and **processes**, **developed** by the operator or **procured** from third parties, that are **certified** under **European cybersecurity certification schemes** adopted under the Cybersecurity Act, in order to demonstrate compliance with cybersecurity risk management measures	x *Not covered*	x *Not covered*
Data Governance & Management	✓ Comply with **fundamental data protection obligations**, including the obligation to carry out a Data Protection Impact Assessment (**DPIA**), as per the GDPR	✓ Ensure that **input data** is **relevant** and **sufficiently representative** in view of the intended purpose of the high-risk AI system, to the extent the deployer exercises control over the input data ✓ **Keep the logs**, to the extent that they are under the deployer's control, **automatically generated** by the high-risk AI system for a period appropriate to the intended purpose of the high-risk AI system	✓ **Refrain** from **using the data** requested from data holders **to develop** a **connected product** that competes with the connected product from which the data originate, **and from sharing the data with a third party** with that intent ✓ **Refrain from using data** to **derive insights** about the economic situation, assets and production methods of the manufacturer or, where applicable the data holder ✓ Refrain from using data for the **profiling**, unless necessary to provide service requested by user; share data with other third parties or to a designated gatekeeper under the DSA

Regulatory intersection

How do the EU's cyber and digital laws intersect?

*The analyzed legislation requires entities to **demonstrate compliance with ICT security requirements.***

*NIS2 provides that Member States **may require** essential and important entities to use particular ICT products, ICT services and ICT processes, either developed by the entity or procured from third parties, that are **certified under European cybersecurity certification schemes** adopted pursuant to Article 49 of Regulation (EU) 2019/881. In the absence of appropriate European cybersecurity certification schemes, Member States shall require entities to comply with **relevant European and international standards** (e.g., upcoming AI standards defined by CEN/CENELEC). Entities shall **oversee the compliance with ICT security requirements by providers** as part of their third-party risk management obligations*

*The analyzed legislation, without prejudice to the overall compliance with **data protection obligations under the GDPR**, requires entities to comply with **additional subject-specific obligations** (e.g., ensuring that input data is relevant and sufficiently representative under the AI Act, and refrain from using or sharing data for purposes that might damage the data holders or users under the Data Act)*

The use case is based on a set of assumptions, as per slide 36, that may not account for all possible scenarios: [1] Essential entity of a type referred to in Annex I; [2]Deployer of a high-risk AI system; [3]Data recipient

Legend: Cybersecurity | Platform economy | AI & Data | Digital finance | Digital identity

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Financial Services – Use Case 1 (1/4)

The Financial Services' use case 1 provides an illustrative snapshot of how a Credit institution is impacted by the identified EU digital and cyber legislation and is based on a set of assumptions that may not account for all possible scenarios

Sector

Financial Services This sector includes financial entities such as: **banking institutions** (i.e., credit institutions) and **financial market infrastructures** (i.e., operators of trading venues and central counterparties, CCPs).

Identification of an entity within the sector

Entity

Credit institution

Definition of the assumptions to build an illustrative use case

Assumptions

Since each legislation imposes specific requirements on entities based on their roles, it is assumed that the Credit institution, under the selected legislation, acts as:

DORA	AI Act	Data Act	MiCA	eIDAS
Default subject to the provisions of DORA Credit institutions are entities that take deposits or other repayable funds from the public and provide loans or credit using their own funds as part of their core business activities. They are included in the scope of the regulation as outlined in Article 2 of DORA.	Provider of a high-risk AI system Any person, organization, or public entity that either creates an AI system or model, or has one created, and then offers it for use or sale under their own name or brand. This can be done whether they charge for it or offer it for free.	Data recipient Any individual or organization acting for purposes related to their trade, business, craft, or profession, excluding the user of a connected product or service, to whom the data holder provides access to data. This may include a third party.	Issuer of asset-referenced tokens Any person, company, or entity that creates and releases crypto-assets.	Trust service provider Any individual or organization that offers trust services, whether they are certified as qualified or not.

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Financial Services – Use Case 1 (2/4)

Credit Institution

Obligations

	DORA[1]	AI Act[2]	Data Act[3]	MiCA[4]	eIDAS[5]
Governance Measures	✓ Establish an **internal governance and control framework** that ensures an effective and prudent management of ICT risk ✓ The **management body** shall **define, approve, oversee and be responsible** for all arrangements related to the **ICT risk management framework** ✓ A **control function** with appropriate level of independence shall be responsible for **managing and overseeing** ICT risk	✓ Put in place and document a **quality management system**, including an accountability framework detailing **roles** and **responsibilities** regarding high-risk AI systems ✓ **Assign human oversight** to natural persons who have the necessary competence, training and authority ✓ Ensure the staff has **adequate AI literacy** ✓ Enforce the **conformity assessment procedure** for high-risk AI systems ✓ Register AI systems and themselves in the EU and, if needed, national **database**	x *Not covered*	✓ Implement **robust governance arrangements**, including a **clear organizational structure** with **well-defined, transparent and consistent lines of responsibility**, effective processes to **identify, manage, monitor and report the risks** to which they are or might be exposed	✓ Take appropriate **organizational measures** to manage risks posed to the security of the trust services provided ✓ Employ **staff** and, if applicable, **subcontractors** who possess the necessary **expertise, reliability, experience, and qualifications** and who have received appropriate training regarding **security and personal data protection rules**
Risk Management & Technical Standards	✓ Implement a **comprehensive and well-documented ICT risk management framework**, including **ICT third-party risk** (i.e., strategies, policies, procedures, ICT protocols to duly and adequately protect all information assets and ICT assets) ✓ Draft and update a **digital operational resilience strategy** setting out how the framework shall be operationalized	✓ Establish, implement, document, and maintain a **risk management system**, namely continuous **iterative process planned and run throughout the entire lifecycle of a high-risk AI system**, to evaluate possible risks ✓ Perform a **fundamental rights impact assessment (FRIA)** for high-risk AI systems before deployment ✓ **Establish and document a post-market monitoring system** that collects, documents and analyses relevant data on the performance of high-risk AI systems throughout their lifetime, including possible risks	x *Not covered*	✓ Implement **internal control mechanisms and effective procedures for risk management**, including effective control and safeguard arrangements for managing **ICT systems** as required by Regulation (EU) 2022/2554 (DORA)	✓ Take appropriate **technical and organizational measures to manage risks** posed to the security of the trust services provided ✓ Use **trustworthy systems and products** that are protected against modification and ensure the **technical security and reliability** of the processes supported by them ✓ Comply with service-specific security **requirements** (e.g., ICT security for electronic signatures)

Regulatory intersection

How do the EU's cyber and digital laws intersect?

*The analyzed legislation requires entities to **review their internal security governance systems** (e.g., cyber/IT security and physical security convergence based on an all-hazard approach), strengthen **accountability of management bodies**, and establish clear **roles and responsibilities** for overseeing and managing ICT-related risks.*

*DORA introduces a general obligation to set a **clear and technology-agnostic risk governance framework, including the obligation to establish a sufficiently independent control function to manage and oversee ICT-related risks.** Other subject-specific legislation introduce **vertical requirements.** Therefore, **compliance** to **vertical requirements contributes** to the fulfillment of **DORA overall governance** obligations.*

*The analyzed legislation requires entities to set up an **ICT-related risk management framework.***

*As the cornerstone legislation for financial entities, **DORA** introduces a broad obligation to set up a **comprehensive, documented and regularly updated risk management framework**, including strategies, policies, procedures, ICT protocols and tools to prevent, detect and manage ICT-related risks. Other **subject-specific risk management obligations** (e.g., under the **AI Act, MiCA** and **eIDAS**) constitute further specifications of the overall risk management obligation imposed by DORA.*

*Therefore, **compliance** with requirements set out in the **AI Act, MiCA,** and **eIDAS contribute** to the fulfillment of **DORA overall ICT-related risk management** obligations.*

The use case is based on a set of assumptions, as per slide 40, that may not account for all possible scenarios: [1]Default subject to the provisions of DORA; [2]Provider of a high-risk AI system; [3]Data recipient; [4]Issuer / Trader of asset-referenced tokens; [5]Trust service provider

Legend: Cybersecurity | Platform economy | AI & Data | Digital finance | Digital identity

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Financial Services – Use Case 1 (3/4)

Credit Institution

Obligations

	DORA[1]	AI Act[2]	Data Act[3]	MiCA[4]	eIDAS[5]
Vulnerability Management	✓ Identify and assess on a continuous basis **cyber threats and ICT vulnerabilities** relevant to ICT supported business functions ✓ Execute **appropriate tests** (e.g., vulnerability assessments, source code reviews, scenario-based and performance testing, end-to-end testing and penetration testing) ✓ Responsibly **disclose vulnerabilities to clients and counterparts** by establishing crisis communication plans	✓ Implement **measures to prevent, detect, respond to, resolve and control for attacks trying to manipulate the training data set**, or pre-trained components used in training, inputs designed to cause the AI model to make a mistake, confidentiality attacks or model flaws	x *Not covered*	x *Not covered*	✓ Perform a regular 2-year **vulnerability assessment to maintain the certification of conformity** for **qualified electronic signature creation devices**
Incident Management	✓ Adopt an **ICT incident management process** to detect, manage, and communicate ICT-related incidents ✓ Report **major ICT-related incidents** to competent authorities established in accordance with article 46	✓ **Notify** to **market surveillance authorities** the occurrence of **serious incidents** that directly or indirectly leads to the death of, or serious harm to, a person, a serious disruption of the management or operation of critical infrastructure, a violation of fundamental rights	x *Not covered*	x *Not covered*	✓ Take appropriate technical and **organizational measures** to prevent and minimize the impact of **security incidents** ✓ Notify **supervisory authority** or other relevant **bodies** within 24h of any **breach of security or loss of integrity** that has a significant impact on the trust service provided or on personal data ✓ Notify the **legal or natural person** to whom the service is provided

Regulatory intersection

How do the EU's cyber and digital laws intersect?

*The analyzed legislation requires entities to implement **appropriate measures** and processes to **manage ICT system vulnerabilities**, such as **periodic vulnerability assessment and penetration testing**, as well as to **record and mitigate** such vulnerabilities either directly or with the involvement of ICT providers.*

*With regard to **AI systems**, providers need to comply with strict monitoring obligations, both ante- and post-market. Other **subject-specific vulnerability management obligations** under **eIDAS** constitute further specifications of the overall vulnerability management obligation imposed by DORA.*

*The analyzed legislation requires entities to set up appropriate measures for **ICT incident management and reporting**.*

*DORA sets a general obligation to **manage incidents throughout their lifecycle** according to recognized standards and frameworks. Hence, entities are expected to manage all incidents related to ICT systems and tools they manufacture or use (e.g., AI systems, software)*

*With regard to **incident reporting obligations under DORA**, Member States are expected to **provide single entry points** at national level. The **AI Act** requires entities to notify **market surveillance authorities** of serious incidents. However, **it is likely that such authorities will coincide with the single-entry points** designated under NIS2. Under eIDAS, entities shall report incidents to competent supervisory authorities which will likely not coincide with single entry points designated under DORA.*

The use case is based on a set of assumptions, as per slide 40, that may not account for all possible scenarios: [1]Default subject to the provisions of DORA; [2]Provider of a high-risk AI system; [3]Data recipient; [4]Issuer / Trader of asset-referenced tokens; [5]Trust service provider

Legend: Cybersecurity | Platform economy | AI & Data | Digital finance | Digital identity

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Financial Services – Use Case 1 (4/4)

Credit Institution

Obligations

	DORA[1]	AI Act[2]	Data Act[3]	MiCA[4]	eIDAS[5]
ICT Security Compliance & Certification	✓ Adopt **ICT systems, protocols, and tools** that are appropriate, reliable, and technologically resilient	✓ Perform a **conformity assessment** to demonstrate compliance with **all requirements for high-risk AI systems,** including **cybersecurity requirements** ✓ Draw up **technical documentation** to demonstrate compliance ✓ Affix the **CE marking**	x *Not covered*	x *Not covered*	✓ Carry out an **audit** by a conformity assessment body at least every 24 months and **submit the resulting conformity assessment report** to competent supervisory authorities ✓ Rely on **cybersecuirty certification schemes** to demonstrate compliance of European Digital Identity Wallets
Data Governance & Management	✓ Adopt ICT systems, protocols and tools equipped with sufficient capacity to **process data** necessary for the performance of activities, as well as to safeguard the **confidentiality, integrity and availability** of data	✓ Ensure that input data is **relevant and sufficiently representative** in view of the intended purpose of the high-risk AI system ✓ Comply with obligation to carry out a **data protection impact assessment** as set out by Regulation 2016/679 (GDPR)	✓ **Refrain** from **using the data** requested from data holders **to develop** a **connected product** that competes with the connected product from which the data originate, **and from sharing the data with a third party** with that intent ✓ **Refrain from using data** to **derive insights** about the economic situation, assets and production methods of the manufacturer or, where applicable the data holder ✓ Refrain from using data for the **profiling**, unless necessary to provide service requested by user; share data with other third parties or to a designated gatekeeper under the DSA	✓ Comply with **fundamental data protection obligations under Union law**	✓ Use **trustworthy systems** to safeguard **confidentiality, integrity, and availability** of data ✓ Take appropriate **measures** against **forgery and theft of data** ✓ Comply with fundamental data obligations outlined in Regulation 2016/679 (GDPR)

Regulatory intersection

How do the EU's cyber and digital laws intersect?

*The analyzed legislation requires entities to **demonstrate compliance with ICT security requirements.***

*DORA provides that entities shall adopt ICT systems, protocols, and tools that are appropriate, reliable, and technologically resilient. The use of ICT systems, protocols or tools that are **certified under European cybersecurity certification schemes** adopted pursuant to Article 49 of Regulation (EU) 2019/881 or **relevant European and international standards** (e.g., upcoming AI standards defined by CEN/CENELEC), contributes to the overall compliance under DORA for the adoption of appropriate, reliable, and technologically resilient ICT systems, protocols or tools*

*The analyzed legislation, without prejudice to the overall compliance with **data protection obligations under the GDPR**, requires entities to comply with **additional subject-specific obligations** (e.g., ensuring that input data is relevant and sufficiently representative under the AI Act, refrain from using or sharing data for purposes that might damage the data holders or users under the Data Act, and taking appropriate measures against forgery and theft of data under eIDAS)*

The use case is based on a set of assumptions, as per slide 40, that may not account for all possible scenarios: [1]Default subject to the provisions of DORA; [2]Provider of a high-risk AI system; [3]Data recipient; [4]Issuer / Trader of asset-referenced tokens; [5]Trust service provider

Legend: Cybersecurity | Platform economy | AI & Data | Digital finance | Digital identity

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Financial Services – Use Case 2 (1/4)

The Financial Services' use case 2 provides an illustrative snapshot of how an Insurance and reinsurance undertaking is impacted by the identified EU digital and cyber legislation and is based on a set of assumptions that may not account for all possible scenarios

Sector

Financial Services: This sector includes financial entities such as: **banking institutions** (i.e., credit institutions) and **financial market infrastructures** (i.e., operators of trading venues and central counterparties, CCPs).

Identification of an entity within the sector

Entity

Insurance and reinsurance undertaking

Definition of the assumptions to build an illustrative use case

Assumptions

Since each legislation imposes specific requirements on entities based on their roles, it is assumed that the Insurance and reinsurance undertaking, under the selected legislation, acts as:

DORA	AI Act	Data Act
Default subject to the provisions of DORA	Deployer of a high-risk AI system	Data recipient
Insurance and reinsurance undertakings are entities authorized to provide direct insurance services (life or non-life) or reinsurance services. They are included in the scope of the regulation as outlined in Article 2 of DORA.	Any individual, organization, government body, agency, or entity using an AI system under its control, unless the AI system is being used for personal, non-professional purposes.	Any individual or organization acting for purposes related to their trade, business, craft, or profession, excluding the user of a connected product or service, to whom the data holder provides access to data. This may include a third party.

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Financial Services – Use Case 2 (2/4)

Insurance and reinsurance undertaking

Obligations

	DORA[1]	AI Act[2]	Data Act[3]
Governance Measures	✓ Establish an **internal governance and control framework** that ensures an effective and prudent management of ICT risk ✓ The **management body** shall **define, approve, oversee and be responsible** for all arrangements related to the **ICT risk management framework** ✓ A **control function** with appropriate level of independence shall be responsible for **managing and overseeing** ICT risk	✓ Take appropriate **organizational measures** to ensure that the use of **high-risk AI systems** is in accordance with the instructions for the use of such system ✓ Ensure the staff has adequate AI literacy ✓ **Assign human oversight to natural persons** who have the necessary competence, training and authority, as well as the necessary support	x *Not covered*
Risk Management & Technical Standards	✓ Implement a **comprehensive and well-documented ICT risk management framework,** including **ICT third-party risk** (i.e., strategies, policies, procedures, ICT protocols to duly and adequately protect all information assets and ICT assets) ✓ Draft and update a **digital operational resilience strategy** setting out how the framework shall be operationalized	✓ Take appropriate **technical measures** to ensure that the use of **high-risk AI systems** is in accordance with the instructions for use ✓ Perform a **fundamental rights impact assessment (FRIA)** for high-risk AI systems before deployment ✓ **Monitor** the **operation of the high-risk AI system** on the basis of the instructions for use and share relevant data with providers and **inform** the **provider or distributor** and relevant **market surveillance authority**, and **suspend the use** of that system in case it poses any **unacceptable risk**	x *Not covered*

Regulatory intersection

How do the EU's cyber and digital laws intersect?

*The analyzed legislation requires entities to **review their internal security governance systems** (e.g., cyber/IT security and physical security convergence based on an all-hazard approach), strengthen **accountability of management bodies**, and establish clear **roles and responsibilities** for overseeing and managing ICT-related risks.*

*Being the cornerstone of cyber resilience legislation for the financial sector, DORA introduces a general obligation to set a **clear and technology-agnostic risk governance framework, including the obligation to establish a sufficiently independent control function to manage and oversee ICT-related risks.** Other subject-specific legislation introduce **vertical requirements.** Therefore, **compliance** to **vertical requirements contributes** to the fulfillment of **DORA overall governance** obligations*

*The analyzed legislation requires entities to set up an **ICT-related risk management framework.***

*As the cornerstone legislation for financial entities, **DORA** introduces a broad obligation to set up a **comprehensive, documented and regularly updated risk management framework**, including strategies, policies, procedures, ICT protocols and tools to prevent, detect and manage ICT-related risks. Other **subject-specific risk management obligations** (e.g., under the **AI Act** and **eIDAS**) constitute further specifications of the overall risk management obligation imposed by DORA.*

*Therefore, **compliance** with requirements set out in the **AI Act** and **eIDAS contribute** to the fulfillment of **DORA overall ICT-related risk management** obligations.*

The use case is based on a set of assumptions, as per slide 44, that may not account for all possible scenarios [1]Default subject to the provisions of DORA; [2]Deployer of a high-risk AI system; [3]Data recipient

Legend: Cybersecurity | Platform economy | AI & Data | Digital finance | Digital identity

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Financial Services – Use Case 2 (3/4)

Insurance and reinsurance undertaking

Obligations

	DORA[1]	AI Act[2]	Data Act[3]
Vulnerability Management	✓ Identify and assess on a continuous basis **cyber threats and ICT vulnerabilities** relevant to ICT supported business functions ✓ Execute **appropriate tests** (e.g., vulnerability assessments, source code reviews, scenario-based and performance testing, end-to-end testing and penetration testing) ✓ Responsibly **disclose vulnerabilities to clients and counterparts** by establishing crisis communication plans	x *Not covered*	x *Not covered*
Incident Management	✓ Adopt an **ICT incident management process** to detect, manage, and communicate ICT-related incidents ✓ Report **major ICT-related incidents** to competent authorities established in accordance with article 46	✓ **Monitor** the **operation of the high-risk AI system** on the basis of the instructions for use and share relevant data with providers within their post-market monitoring activities, including data regarding any **discovered serious incident** ✓ **Inform** first the **provider**, and then the **importer** or **distributor** and the relevant **market surveillance authorities** in case of a **serious incident** as defined in Article 3(49)	x *Not covered*

Regulatory intersection

How do the EU's cyber and digital laws intersect?

*The analyzed legislation requires entities to implement **appropriate measures** and processes to **manage ICT system vulnerabilities**, such as **periodic vulnerability assessment and penetration testing**, as well as to **record and mitigate** such vulnerabilities either directly or with the involvement of ICT providers.*

*With regard to **AI systems**, **deployers cannot directly test the infrastructure** of the AI system. It is likely that they will oversee the overall security of the AI system through their **overall third-party risk management framework** (e.g. reviewing supply chains and negotiating specific contractual clauses).*

*The analyzed legislation requires entities to set up appropriate measures for **ICT incident management and reporting**.*

*DORA sets a general obligation to manage incidents throughout their lifecycle according to recognized standards and frameworks, covering analogous product-specific obligations (e.g., under the CRA) With regard to **incident reporting obligations under DORA,** Member States are expected to **provide single entry points** at national level to alleviate administrative burden. The **AI Act** requires entities to notify **market surveillance authorities** of serious incidents. However, **it is likely that such authorities will coincide with the single-entry points** designated under NIS2, in order to streamline reporting obligations.*

The use case is based on a set of assumptions, as per slide 44, that may not account for all possible scenarios [1]Default subject to the provisions of DORA; [2]Deployer of a high-risk AI system; [3]Data recipient

Legend: Cybersecurity | Platform economy | AI & Data | Digital finance | Digital identity

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Financial Services – Use Case 2 (4/4)

Insurance and reinsurance undertaking

Obligations

	DORA[1]	AI Act[2]	Data Act[3]
ICT Security Compliance & Certification	✓ Adopt **ICT systems, protocols, and tools** that are appropriate, reliable, and technologically resilient	x *Not covered*	x *Not covered*
Data Governance & Management	✓ Adopt ICT systems, protocols and tools equipped with sufficient capacity to **process data** necessary for the performance of activities, as well as to safeguard the **confidentiality, integrity and availability** of data	✓ Ensure that **input data** is **relevant** and **sufficiently representative** in view of the intended purpose of the high-risk AI system, to the extent the deployer exercises control over the input data ✓ **Keep the logs**, to the extent that they are under the deployer's control, **automatically generated** by the high-risk AI system for a period appropriate to the intended purpose of the high-risk AI system	✓ **Refrain** from **using the data** requested from data holders **to develop** a **connected product** that competes with the connected product from which the data originate, **and from sharing the data with a third party** with that intent ✓ **Refrain from using data** to **derive insights** about the economic situation, assets and production methods of the manufacturer or, where applicable the data holder ✓ Refrain from using data for the **profiling**, unless necessary to provide service requested by user; share data with other third parties or to a designated gatekeeper under the DSA

Regulatory intersection

How do the EU's cyber and digital laws intersect?

*The analyzed legislation requires entities to **demonstrate compliance with ICT security requirements.***

*DORA provides that entities shall adopt ICT systems, protocols, and tools that are appropriate, reliable, and technologically resilient. The use of ICT systems, protocols or tools that are **certified under European cybersecurity certification schemes** adopted pursuant to Article 49 of Regulation (EU) 2019/881 or **relevant European and international standards** (e.g., upcoming AI standards defined by CEN/CENELEC), contributes to the overall compliance under DORA for the adoption of appropriate, reliable, and technologically resilient ICT systems, protocols or tools*

*The analyzed legislation, without prejudice to the overall compliance with **data protection obligations under the GDPR**, requires entities to comply with **additional subject-specific obligations** (e.g., ensuring that input data is relevant and sufficiently representative under the AI Act, refrain from using or sharing data for purposes that might damage the data holders or users under the Data Act).*

The use case is based on a set of assumptions, as per slide 44, that may not account for all possible scenarios [1]Default subject to the provisions of DORA; [2]Deployer of a high-risk AI system; [3]Data recipient

Legend: Cybersecurity | Platform economy | AI & Data | Digital finance | Digital identity

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Government & Public Services – Use Case 1 (1/4)

The Government & Public Services' use case 1 provides an illustrative snapshot of how a Public healthcare service provider is impacted by the identified EU digital and cyber legislation and is based on a set of assumptions that may not account for all possible scenarios

Sector

Government & Public Services. This sector includes central and local **governments, public administration** entities, and **public services** (e.g., public healthcare, transport, education).

Identification of an entity within the sector

Entity

Public healthcare service provider (Public Hospital)

Definition of the assumptions to build an illustrative use case

Assumptions

Since each legislation imposes specific requirements on entities based on their roles, it is assumed that the Public healthcare service provider, under the selected legislation, acts as:

NIS2	MDR	AI Act	DGA	EHDS
Essential entity	Public health institution	Deployer of a high-risk AI system	Public sector body	Manufacturer
An entity referred to in Annex I "Sectors of High Criticality," which exceeds the ceilings for medium-sized enterprises.	Public organization primarily focused on caring for or treating patients or promoting public health.	Any individual, organization, government body, agency, or entity using an AI system under its control, unless the AI system is being used for personal, non-professional purposes.	Government organizations at the national, regional, or local level, as well as organizations controlled by public law or associations made up of such authorities or organizations.	Healthcare provider as 'in house' developer and user of EHR system.

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Government & Public Services – Use Case 1 (2/4)

Public healthcare service provider (Public Hospital)

Obligations

	NIS2[1]	MDR[2]	AI Act[3]	DGA[4]	EHDS[5]
Governance Measures	✓ Establish appropriate and proportionate **governance measures**, i.e. accountability of management bodies for cybersecurity risk management measures ✓ Establish appropriate and proportionate **organizational measures** based on an **all-hazards approach** to manage cybersecurity related **risks**	x *Not covered*	✓ Take appropriate **organizational measures** to ensure that the use of **high-risk AI systems** is in accordance with the instructions for the use of such system ✓ Ensure the staff has adequate AI literacy ✓ **Assign human oversight to natural persons** who have the necessary competence, training and authority, as well as the necessary support	x *Not covered*	x *Not covered*
Risk Management & Technical Standards	✓ Establish appropriate and proportionate **technical and operational measures to manage cybersecurity related risks**, e.g., adopt adequate policies, including business continuity and disaster recovery, third-party and supply chain security, ensure security in network and information systems acquisition, development and maintenance, adopt basic cyber hygiene practices and cybersecurity training, use of multi-factor authentication or continuous authentication solutions	✓ **Establish**, **implement**, **document** and maintain a **risk management system** ✓ **Design** and **manufacture medical devices** to **remove** or reduce **risks**, including residual risks, associated with **identified hazard** ✓ Set out **minimum requirements** concerning **hardware**, **IT networks characteristics** and **IT security measures**, including protection against unauthorised access	✓ Take appropriate **technical measures** to ensure that the use of **high-risk AI systems** is in accordance with the instructions for use ✓ Perform a **fundamental rights impact assessment (FRIA)** for high-risk AI systems before deployment ✓ **Monitor** the **operation of the high-risk AI system** on the basis of the instructions for use and share relevant data with providers and **inform** the **provider or distributor** and relevant **market surveillance authority**, and **suspend the use** of that system in case it poses any **unacceptable risk**	x *Not covered*	x *Not covered*

Regulatory intersection

How do the EU's cyber and digital laws intersect?

*The analyzed legislation requires entities to **review their internal security governance systems** (e.g., cyber/IT security and physical security convergence based on an all-hazard approach), strengthen **accountability of management bodies**, and establish clear **roles and responsibilities** for overseeing and managing ICT-related risks.*

*Being a horizontal legislation, **NIS2** introduces a general obligation to set a **clear and technology-agnostic risk governance framework**, while subject-specific legislation – such as the AI Act – introduces **vertical requirements**.*

*Therefore, **compliance** to high-risk AI systems **vertical requirements contributes** to the fulfillment of **NIS2 overall governance** obligations*

*The analyzed legislation requires entities to set up an **ICT-related risk management framework.***

*As a horizontal legislation, NIS2 introduces a broad obligation to set up a **comprehensive, documented and regularly updated risk management framework**, including strategies, policies, procedures, ICT protocols and tools to prevent, detect and manage ICT-related risks. **Medical devices** and **AI systems** used by the entity, being tools, shall be included in the risk management framework, with, respectively, their design and manufacture, as well as implementation and use being documented in adequate policies, as well within the entity's **overall third-party risk management process** (e.g., supply chain mapping, contract review). Therefore, **compliance** to medical devices and high-risk AI systems **vertical requirements contributes** to the fulfillment of **NIS2 overall ICT-related risk management** obligations*

The use case is based on a set of assumptions, as per slide 48, that may not account for all possible scenarios: [1]Essential entity of a type referred to in Annex I; [2]Public health institution; [3]Deployer of a high-risk AI system; [4]Public sector body; [5]Manufacturer (healthcare provider as 'in house' developer and user of EHR system)

Legend Cybersecurity | Platform economy | AI & Data | Digital finance | Digital identity

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Government & Public Services – Use Case 1 (3/4)

Public healthcare service provider (Public Hospital)

Obligations

	NIS2[1]	MDR[2]	AI Act[3]	DGA[4]	EHDS[5]
Vulnerability Management	✓ Establish appropriate and proportionate **technical** and **operational measures** to **manage vulnerabilities** and **report** them to the **national CSIRT** an, where needed, to **service recipients** ✓ Take into account **vulnerabilities** specific to **direct suppliers** and **service providers** and the overall **quality of their products** and cybersecurity **practices**	x *Not covered*	x *Not covered*	x *Not covered*	x *Not covered*
Incident Management	✓ Establish appropriate and proportionate **technical** and **operational** measures for **incident handling** ✓ Establish **business continuity** measures, such as backup management and **disaster recovery**, and **crisis management** ✓ Notify to **national CSIRT**, or **competent authority**, any **incident** that has a **significant impact** on the provision of the operator's services	x *Not covered*	✓ **Monitor** the **operation of the high-risk AI system** on the basis of the instructions for use and share relevant data with providers within their post-market monitoring activities, including data regarding any **discovered serious incident** ✓ **Inform** first the **provider**, and then the **importer** or **distributor** and the relevant **market surveillance authorities** in case of a **serious incident** as defined in Article 3(49)	x *Not covered*	✓ Notify to **market surveillance authorities** any **incident** involving an **EHR system** and the **corrective action taken** or **envisaged** by the manufacturer, without prejudice to **incident notification requirements** under **NIS2** Directive ✓ Comply with **data breach notifications** under the **GDPR**

Regulatory intersection

How do the EU's cyber and digital laws intersect?

*The analyzed legislation requires entities to implement **appropriate measures** and processes to **manage ICT system vulnerabilities**, such as **periodic vulnerability assessment and penetration testing**, as well as to **record and mitigate** such vulnerabilities either directly or with the involvement of ICT providers.*

*With regard to **AI systems**, **deployers cannot directly test the infrastructure** of the AI system. It is likely that they will oversee the overall security of the AI system through their **overall third-party risk management framework** (e.g. reviewing supply chains and negotiating specific contractual clauses)*

*The analyzed legislation requires entities to set up appropriate measures for **ICT incident reporting** and **handling**.*

*While NIS2 outlines measures for the notification of **ICT significant incidents** to national CSIRTs, or competent authorities, the AI Act outlines measures for the notification of **serious incidents** to **market surveillance authorities**, and EHDS provides measures for the notification of incidents regarding **EHR systems** to **market surveillance authorities.***

*The legislation aims to **simplify** and **streamline** reporting procedures by encouraging the establishment of national **single-entry points** for the fulfillment of reporting requirements. Currently, the **AI Act** falls **outside such requirements** and envisages notification procedures towards **market surveillance authorities.** However, such authorities are **encouraged to correspond to single entry points***

The use case is based on a set of assumptions, as per slide 48, that may not account for all possible scenarios: [1]Essential entity of a type referred to in Annex I; [2]Public health institution; [3]Deployer of a high-risk AI system; [4]Public sector body; [5]Manufacturer (healthcare provider as 'in house' developer and user of EHR system)

Legend: Cybersecurity | Platform economy | AI & Data | Digital finance | Digital identity

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Government & Public Services – Use Case 1 (4/4)

Public healthcare service provider (Public Hospital)

Obligations

	NIS2[1]	MDR[2]	AI Act[3]	DGA[4]	EHDS[5]
ICT Security Compliance & Certification	✓ ***May*** be required to use **IT/OT products**, **services** and **processes**, **developed** by the operator or **procured** from third parties, that are **certified** under **European cybersecurity certification schemes** adopted under the Cybersecurity Act, in order to demonstrate compliance with cybersecurity risk management measures	x *Not covered*	x *Not covered*	x *Not covered*	✓ Ensure **conformity** of the **harmonised components of EHR systems** and EHR systems as such with the essential requirements and the common specifications ✓ **Draw up technical documentation** to demonstrate compliance ✓ Affix the **CE marking**
Data Governance & Management	✓ Comply with **fundamental data protection obligations**, including the obligation to carry out a Data Protection Impact Assessment (**DPIA**), as per the GDPR	x *Not covered*	✓ Ensure that **input data** is **relevant** and **sufficiently representative** in view of the intended purpose of the high-risk AI system, to the extent the deployer exercises control over the input data ✓ **Keep the logs**, to the extent that they are under the deployer's control, **automatically generated** by the high-risk AI system for a period appropriate to the intended purpose of the high-risk AI system	✓ Ensure that all the **conditions** for the **re-use of data**, for which the public sector body is competent, are satisfied, e.g., ensure that the protected nature of data is preserved ✓ Make **publicly available** the **conditions** for **allowing** the **re-use of data** and the procedure to request the re-use via the single information point	✓ Ensure that the **harmonised components of EHR systems** and products claiming interoperability with EHR systems (i.e., AI systems) comply with the **essential requirements** for **interoperability** and for **security** and **for logging** ✓ Comply with **data obligations** outlined in the **GDPR**

Regulatory intersection

How do the EU's cyber and digital laws intersect?

*The analyzed legislation requires entities to **demonstrate compliance with ICT security requirements.***

*NIS2 provides that Member States **may require** essential and important entities to use particular ICT products, ICT services and ICT processes, either developed by the entity or procured from third parties, that are **certified under European cybersecurity certification schemes** adopted pursuant to Article 49 of Regulation (EU) 2019/881. In the absence of appropriate European cybersecurity certification schemes, Member States shall require entities to comply with **relevant European and international standards** (e.g., upcoming AI standards defined by CEN/CENELEC and standardization of cybersecurity requirements under CRA)*

*The analyzed legislation, without prejudice to the overall compliance with **data protection obligations under the GDPR**, requires entities to comply with **additional subject-specific obligations** (e.g., ensuring that input data is relevant and sufficiently representative under the AI Act, making publicly available the conditions for allowing the re-use of data under the DGA, and ensuring compliance with interoperability, security and logging requirements under the EHDS)*

The use case is based on a set of assumptions, as per slide 48, that may not account for all possible scenarios: [1]Essential entity of a type referred to in Annex I; [2]Public health institution; [3]Deployer of a high-risk AI system; [4]Public sector body; [5]Manufacturer (healthcare provider as 'in house' developer and user of EHR system)

Legend Cybersecurity | Platform economy | AI & Data | Digital finance | Digital identity

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Life Sciences & Healthcare – Use Case 1 (1/4)

The Life Sciences & Healthcare's use case 1 provides an illustrative snapshot of how a Manufacturer of basic pharmaceutical products and pharmaceutical preparations is impacted by the identified EU digital and cyber legislation and is based on a set of assumptions that may not account for all possible scenarios

Sector

Life Sciences & Healthcare. This sector includes public and private entities such as **healthcare service providers**, EU reference **laboratories**, **research and development** of **medicinal products**, manufacture of **pharmaceutical products** and **pharmaceutical preparations.**

Identification of an entity within the sector

Entity

Manufacturer of basic pharmaceutical products and pharmaceutical preparations

Definition of the assumptions to build an illustrative use case

Assumptions

Since each legislation imposes specific requirements on entities based on their roles, it is assumed that the Manufacturer of basic pharmaceutical products and pharmaceutical preparations, under the selected legislation, acts as:

NIS2	AI Act
Essential entity	Deployer of a high-risk AI system
An entity referred to in Annex I "Sectors of High Criticality," which exceeds the ceilings for medium-sized enterprises.	Any individual, organization, government body, agency, or entity using an AI system under its control, unless the AI system is being used for personal, non-professional purposes.

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Life Sciences & Healthcare* – Use Case 1 (2/4)

Manufacturer of basic pharmaceutical products and pharmaceutical preparations

Obligations

	NIS2[1]	AI Act[2]
Governance Measures	✓ Establish appropriate and proportionate **governance measures**, i.e. accountability of management bodies for cybersecurity risk management measures ✓ Establish appropriate and proportionate **organizational measures** based on an **all-hazards approach** to manage cybersecurity related **risks**	✓ Take appropriate **organizational measures** to ensure that the use of **high-risk AI systems** is in accordance with the instructions for the use of such system ✓ Ensure the staff has adequate AI literacy ✓ **Assign human oversight to natural persons** who have the necessary competence, training and authority, as well as the necessary support
Risk Management & Technical Standards	✓ Establish appropriate and proportionate **technical and operational measures to manage cybersecurity related risks**, e.g., adopt adequate policies, including business continuity and disaster recovery, third-party and supply chain security, ensure security in network and information systems acquisition, development and maintenance, adopt basic cyber hygiene practices and cybersecurity training, use of multi-factor authentication or continuous authentication solutions	✓ Take appropriate **technical measures** to ensure that the use of **high-risk AI systems** is in accordance with the instructions for use ✓ Perform a **fundamental rights impact assessment (FRIA)** for high-risk AI systems before deployment ✓ **Monitor** the **operation of the high-risk AI system** on the basis of the instructions for use and share relevant data with providers and **inform** the **provider or distributor** and relevant **market surveillance authority**, and **suspend the use** of that system in case it poses any **unacceptable risk**

Regulatory intersection

How do the EU's cyber and digital laws intersect?

*The analyzed legislation requires entities to **review their internal security governance systems** (e.g., cyber/IT security and physical security convergence based on an all-hazard approach), strengthen **accountability of management bodies**, and establish clear **roles and responsibilities** for overseeing and managing ICT-related risks.*

*Being a horizontal legislation, **NIS2** introduces a general obligation to set a **clear and technology-agnostic risk governance framework**, while subject-specific legislation – such as the AI Act – introduces **vertical requirements**.*

*Therefore, **compliance** to high-risk AI systems **vertical requirements contributes** to the fulfillment of **NIS2 overall governance** obligations*

*As a horizontal legislation, NIS2 introduces a broad obligation to set up a **comprehensive, documented and regularly updated risk management framework**, namely strategies, policies, procedures, ICT protocols and tools to prevent, detect and manage ICT-related risks. **AI systems** used by the entity, being tools, shall be included in the risk management framework, with their implementation and use being documented in adequate policies, as well within the entity's **overall third-party risk management process** (e.g., supply chain mapping, contract review)*

The use case is based on a set of assumptions, as per slide 52, that may not account for all possible scenarios:
[1]Essential entity of a type referred to in Annex I; [2]Deployer of high-risk AI system

*According to research, **young people** consider **life sciences and healthcare** the **priority areas** where **STEM disciplines** can offer the greatest contribution to tackle **major challenges** of the future

Legend: Cybersecurity | Platform economy | AI & Data | Digital finance | Digital identity

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Life Sciences & Healthcare – Use Case 1 (3/4)

Manufacturer of basic pharmaceutical products and pharmaceutical preparations

Obligations

	NIS2[1]	AI Act[2]	Regulatory intersection: *How do the EU's cyber and digital laws intersect?*
Vulnerability Management	✓ Establish appropriate and proportionate **technical** and **operational measures** to **manage vulnerabilities** and **report** them to the **national CSIRT** an, where needed, to **service recipients** ✓ Take into account **vulnerabilities** specific to **direct suppliers** and **service providers** and the overall **quality of their products** and cybersecurity **practices**	x *Not covered*	*The analyzed legislation requires entities to implement **appropriate measures** and processes to **manage ICT system vulnerabilities**, such as **periodic vulnerability assessment and penetration testing**, as well as to **record and mitigate** such vulnerabilities either directly or with the involvement of ICT providers.* *With regard to **AI systems**, **deployers cannot directly test the infrastructure** of the AI system. It is likely that they will oversee the overall security of the AI system through their **overall third-party risk management framework** (e.g. reviewing supply chains and negotiating specific contractual clauses)*
Incident Management	✓ Establish appropriate and proportionate **technical** and **operational** measures for **incident handling** ✓ Establish **business continuity** measures, such as backup management and **disaster recovery**, and **crisis management** ✓ Notify to **national CSIRT**, or **competent authority**, any **incident** that has a **significant impact** on the provision of the operator's services	✓ **Monitor** the **operation of the high-risk AI system** on the basis of the instructions for use and share relevant data with providers within their post-market monitoring activities, including data regarding any **discovered serious incident** ✓ **Inform** first the **provider**, and then the **importer** or **distributor** and the relevant **market surveillance authorities** in case of a **serious incident** as defined in Article 3(49)	*The analyzed legislation requires entities to set up appropriate measures for **ICT incident reporting** and **handling**.* *While NIS2 outlines measures for the notification of **ICT significant incidents** to national CSIRTs, or competent authorities, the AI Act outlines measures for the notification of **serious incidents** to **market surveillance authorities.*** *The legislation aims to **simplify** and **streamline** reporting procedures by encouraging the establishment of national **single-entry points** for the fulfillment of reporting requirements. Currently, the **AI Act** falls **outside such requirements** and envisages notification procedures towards **market surveillance authorities.** However, such authorities are **encouraged to correspond to single entry points***

The use case is based on a set of assumptions, as per slide 52, that may not account for all possible scenarios:
[1]Essential entity of a type referred to in Annex I; [2]Deployer of high-risk AI system

*According to research, **young people** consider **life sciences and healthcare** the **priority areas** where **STEM disciplines** can offer the greatest contribution to tackle **major challenges** of the future

Legend: Cybersecurity | Platform economy | AI & Data | Digital finance | Digital identity

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Life Sciences & Healthcare – Use Case 1 (4/4)

Manufacturer of basic pharmaceutical products and pharmaceutical preparations

Obligations

	NIS2[1]	AI Act[2]	Regulatory intersection
ICT Security Compliance & Certification	✓ ***May*** be required to use **IT/OT products**, **services** and **processes**, **developed** by the operator or **procured** from third parties, that are **certified** under **European cybersecurity certification schemes** adopted under the Cybersecurity Act, in order to demonstrate compliance with cybersecurity risk management measures	x *Not covered*	*The analyzed legislation requires entities to **demonstrate compliance with ICT security requirements.*** *NIS2 provides that Member States **may require** essential and important entities to use particular ICT products, ICT services and ICT processes, either developed by the entity or procured from third parties, that are **certified under European cybersecurity certification schemes** adopted pursuant to Article 49 of Regulation (EU) 2019/881. In the absence of appropriate European cybersecurity certification schemes, Member States shall require entities to comply with **relevant European and international standards** (e.g., upcoming AI standards defined by CEN/CENELEC)*
Data Governance & Management	✓ Comply with **fundamental data protection obligations**, including the obligation to carry out a Data Protection Impact Assessment (**DPIA**), as per the GDPR	✓ Ensure that **input data** is **relevant** and **sufficiently representative** in view of the intended purpose of the high-risk AI system, to the extent the deployer exercises control over the input data ✓ **Keep the logs**, to the extent that they are under the deployer's control, **automatically generated** by the high-risk AI system for a period appropriate to the intended purpose of the high-risk AI system	*The analyzed legislation, without prejudice to the overall compliance with **data protection obligations under the GDPR**, requires entities to comply with **additional subject-specific obligations** (e.g., ensuring that input data is relevant and sufficiently representative under the AI Act)*

The use case is based on a set of assumptions, as per slide 52, that may not account for all possible scenarios:
[1]Essential entity of a type referred to in Annex I; [2]Deployer of high-risk AI system

*According to research, **young people** consider **life sciences and healthcare** the **priority areas** where **STEM disciplines** can offer the greatest contribution to tackle **major challenges** of the future

Legend: Cybersecurity | Platform economy | AI & Data | Digital finance | Digital identity

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Manufacturing & Consumer – Use Case 1 (1/4)

The Manufacturing & Consumer's use case 1 provides an illustrative snapshot of how a Manufacturer of air and spacecraft and related machinery is impacted by the identified EU digital and cyber legislation and is based on a set of assumptions that may not account for all possible scenarios

Sector

Manufacturing & Consumer. This sector includes public and private entities operating in the following industries: **manufacturing** of **medical devices**, **computer**, **electronic** and **optical products**, **electrical equipment**, **machinery**, **motor vehicles**, trailers and semi-trailers, other **transportation equipment**, **manufacturing** of **consumer products.**

Identification of an entity within the sector

Entity

Manufacturer of air and spacecraft and related machinery (for Defense purposes)

Definition of the assumptions to build an illustrative use case

Assumptions

Since each legislation imposes specific requirements on entities based on their roles, it is assumed that the Manufacturer of air and spacecraft and related machinery, under the selected legislation, acts as:

CRA	NIS2	RED	AI Act	Data Act
Manufacturer	Important entity	Manufacturer	Deployer of a high-risk AI system	Data holder
An entity that creates or produces products with digital components, or has them made, and then sells or distributes them under their own name or brand, whether for payment, profit or for free.	An entity referred to in Annex II "Other Critical Sectors" considering the "Manufacture of other transport equipment" subsector, which includes the selected entity as undertakings carrying out any of the economic activities referred to in section C division 30 of NACE Rev. 2.*	Any person or company that makes radio equipment or has it designed or produced, and then sells or distributes it under their own name or brand.	Any individual, organization, government body, agency, or entity using an AI system under its control, unless the AI system is being used for personal, non-professional purposes.	A person or organization that has the right or responsibility, under this regulation or other relevant laws, to use and share data. This can include product or service data that they have gathered or created while providing a service, if agreed upon in a contract.

*NACE Rev. 2. Statistical classification of economic activities in the European Community: https://ec.europa.eu/eurostat/documents/3859598/5902521/KS-RA-07-015-EN.PDF

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Manufacturing & Consumer – Use Case 1 (2/4)

Manufacturer of air and spacecraft and related machinery (for Defense purposes)

Obligations

	CRA[1]	NIS2[2]	RED[3]	AI Act[4]	Data Act[5]
Governance Measures	✓ Establish and document a **quality system** that describes, inter alia, the **organizational structure, responsibilities and powers of the management** with regard to design, development, product quality and vulnerability handling of a product with digital elements	✓ Establish appropriate and proportionate **governance measures**, i.e. accountability of management bodies for cybersecurity risk management measures ✓ Establish appropriate and proportionate **organizational measures** based on an **all-hazards approach** to manage cybersecurity related **risks**	✓ Implement a quality system which, inter alia, describes the **quality objectives** and the **organizational structure, responsibilities and powers of the management** with regard to design and product quality	✓ Take appropriate **organizational measures** to ensure that the use of **high-risk AI systems** is in accordance with the instructions for the use of such system ✓ Ensure the staff has adequate AI literacy ✓ **Assign human oversight to natural persons** who have the necessary competence, training and authority, as well as the necessary support	x *Not covered*
Risk Management & Technical Standards	✓ Ensure that the **product** with digital elements has been **designed**, **developed** and **produced** in accordance with the **essential cybersecurity requirements,** of both **products** and **processes**, i.e. undertake an assessment of the **cybersecurity risks** associated with a product with digital elements and take the outcome of that assessment during the product's lifecycle	✓ Establish appropriate and proportionate **technical and operational measures to manage cybersecurity related risks**, e.g., adopt adequate policies, including business continuity and disaster recovery, third-party and supply chain security, ensure security in network and information systems acquisition, development and maintenance, adopt basic cyber hygiene practices and cybersecurity training, use of multi-factor authentication or continuous authentication solutions	✓ Ensure that **radio equipment complies with essential security requirements**	✓ Take appropriate **technical measures** to ensure that the use of **high-risk AI systems** is in accordance with the instructions for use ✓ Perform a **fundamental rights impact assessment (FRIA)** for high-risk AI systems before deployment ✓ **Monitor** the **operation of the high-risk AI system** on the basis of the instructions for use and share relevant data with providers. If the use of the high-risk AI system presents a risk, the deployer shall **inform** the **provider or distributor**, the relevant **market surveillance authority**, and **suspend the use** of that system	✓ ***May*** apply appropriate **technical protection measures**, including smart contracts and encryption, to prevent **unauthorized access to data**, including metadata, and to ensure compliance with data sharing obligations and with the agreed contractual terms for making data available

Regulatory intersection

How do the EU's cyber and digital laws intersect?

*The analyzed legislation requires entities to **review their internal security governance systems** (e.g., cyber/IT security and physical security convergence based on an all-hazard approach), strengthen **accountability of management bodies**, and establish clear **roles and responsibilities** for overseeing and managing ICT-related risks.*

*Being a horizontal legislation, **NIS2** introduces a general obligation to set a **clear and technology-agnostic risk governance framework**, while subject-specific legislation – such as the CRA, RED and AI Act – introduces **vertical requirements**.*

*Therefore, **compliance** to, respectively, products with digital elements, radio equipment and high-risk AI systems **vertical requirements contributes** to the fulfillment of **NIS2 overall governance** obligations*

*The analyzed legislation requires entities to set up an **I-elated risk management framework.***

*As a horizontal legislation, NIS2 introduces a broad obligation to set up a **comprehensive, documented and regularly updated risk management framework**, namely strategies, policies, procedures, ICT protocols and tools to prevent, detect and manage ICT-related risks. With specific regard to **essential requirements of products with digital elements**, the **Cyber Resilience Act applies to radio equipment** in scope of the RED Directive (and Delegated Regulation): hence, **CRA requirements align with those of RED,** depending on specific requirements.*

*Finally, **deployers** of high-risk AI systems shall take appropriate **technical measures**. Also, they shall **monitor the use** of such systems. If risks arise, they shall **notify** relevant stakeholders and **suspend** the use of the system.*

The use case is based on a set of assumptions, as per slide 56, that may not account for all possible scenarios: [1]Manufacturer; [2]Important entity of a type referred to in Annex II; [3]Manufacturer; [4]Deployer of a high-risk AI system; [5]Data holder

Legend: Cybersecurity | Platform economy | AI & Data | Digital finance | Digital identity

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Manufacturing & Consumer – Use Case 1 (3/4)

Manufacturer of air and spacecraft and related machinery (for Defense purposes)

Obligations

	CRA[1]	NIS2[2]	RED[3]	AI Act[4]	Data Act[5]
Vulnerability Management	✓ Ensure that the **product** with digital elements has been **designed**, **developed** and **produced** in accordance with **vulnerability handling requirements**, i.e. establish appropriate vulnerability disclosure policies ✓ **Notify** any **actively exploited vulnerability** contained in the product with digital elements to the national **CSIRT** designated as coordinator and to **ENISA** via the **single reporting platform**	✓ Establish appropriate and proportionate **technical** and **operational measures** to **manage vulnerabilities** and **report** them to the **national CSIRT** an, where needed, to **service recipients** ✓ Take into account **vulnerabilities** specific to **direct suppliers** and **service providers** and the overall **quality of their products** and cybersecurity **practices**	x *Not covered*	x *Not covered*	x *Not covered*
Incident Management	✓ Ensure that the **product** with digital elements has been **designed**, **developed** and **produced** in accordance with essential cybersecurity requirements **to prevent incidents and minimize their impact** ✓ **Notify** any **severe incident** having an impact on the security of the product with digital elements to the **CSIRT** designated as coordinator and to **ENISA** via the **single reporting platform**	✓ Establish appropriate and proportionate **technical** and **operational** measures for **incident handling** ✓ Establish **business continuity** measures, such as backup management and **disaster recovery**, and **crisis management** ✓ Notify to **national CSIRT**, or **competent authority**, any **incident** that has a **significant impact** on the provision of the operator's services	x *Not covered*	✓ **Monitor** the **operation of the high-risk AI system** on the basis of the instructions for use and share relevant data with providers within their post-market monitoring activities, including data regarding any **discovered serious incident** ✓ **Inform** first the **provider**, and then the **importer** or **distributor** and the relevant **market surveillance authorities** in case of a **serious incident** as defined in Article 3(49)	✓ In case of **emergencies** and **major disasters**, such as **major cybersecurity incidents**, data holders shall **make data available to public sector bodies**, the Commission, the European Central Bank or Union bodies upon their request

Regulatory intersection

How do the EU's cyber and digital laws intersect?

*The analyzed legislation requires entities to implement **appropriate measures** and **processes** to **manage ICT system vulnerabilities**, such as **periodic vulnerability assessment and penetration testing**, as well as to **record and mitigate** such vulnerabilities either directly or with the involvement of ICT providers.*

*Obligations under the **CRA** are strictly complementary to the fulfillment of **NIS2**. Thus, compliance with the former contributes to the overall compliance of the latter.*

*With regard to **reporting obligations**, Member States expected to **provide single entry points** at national level to alleviate administrative burden on entities*

*The analyzed legislation requires entities to set up appropriate measures for **ICT incident management and reporting**. **NIS2** sets a general obligation to manage incidents throughout their lifecycle according to recognized standards and frameworks, covering analogous product-specific obligations (e.g., under the **CRA**) .*

*With regard to **incident reporting obligations under NIS2 and CRA**, Member States expected to **provide single entry points** at national level to alleviate administrative burden. The **AI Act** requires entities to notify **market surveillance authorities** of serious incidents. However, **it is to be considered that possibly such authorities will coincide with the single-entry points** designated under **NIS2**, in order to streamline reporting obligations*

*Finally, in case of **major cybersecurity incidents**, entities shall **make data available** to **public sector bodies** and **Union bodies**.*

The use case is based on a set of assumptions, as per slide 56, that may not account for all possible scenarios: [1]Manufacturer; [2]Important entity of a type referred to in Annex II; [3]Manufacturer; [4]Deployer of a high-risk AI system; [5]Data holder

Legend Cybersecurity | Platform economy | AI & Data | Digital finance | Digital identity

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Manufacturing & Consumer – Use Case 1 (4/4)

Manufacturer of air and spacecraft and related machinery (for Defense purposes)

Obligations

	CRA[1]	NIS2[2]	RED[3]	AI Act[4]	Data Act[5]
ICT Security Compliance & Certification	✓ Perform a **cybersecurity conformity assessment** of **products** and **processes** to demonstrate compliance with essential cybersecurity requirements ✓ Draw up **technical documentation** to demonstrate compliance ✓ Affix the **CE marking** ✓ Identify **"important"** or **"critical" products** with digital elements that are subject to **additional controls** and **conformity assessment procedures**	✓ ***May*** be required to use **IT/OT products**, **services** and **processes**, **developed** by the operator or **procured** from third parties, that are **certified** under **European cybersecurity certification schemes** adopted under the Cybersecurity Act, in order to demonstrate compliance with cybersecurity risk management measures	✓ Ensure that **radio equipment** comply with essential requirements set out in Article 3, RED and Delegate Regulation 2022/30 ✓ Provide the Member States and the Commission with information on the compliance of **intended combinations of radio equipment and software** resulting from a **conformity assessment** in the form of a statement of compliance (EU declaration of conformity)	x *Not covered*	x *Not covered*
Data Governance & Management	✓ **Safeguard** the Confidentiality, Integrity and Availability (**CIA**) of processed data ✓ **Ensure** the **possibility** for **users** to securely and easily **remove** on a permanent basis **all data and settings** ✓ Ensure **data portability**	✓ Comply with **fundamental data protection obligations**, including the obligation to carry out a Data Protection Impact Assessment (**DPIA**), as per the GDPR	✓ Radio equipment has to incorporate safeguards to ensure that the **personal data and privacy** of the user and of the subscriber **are protected**	✓ Ensure that **input data** is **relevant** and **sufficiently representative** in view of the intended purpose of the high-risk AI system, to the extent the deployer exercises control over the input data ✓ **Keep the logs**, to the extent that they are under the deployer's control, **automatically generated** by the high-risk AI system for a period appropriate to the intended purpose of the high-risk AI system	✓ Make data available to users or to a party acting on user's behalf **easily, securely, free of charge**, **in a comprehensive, structured, commonly used and machine-readable format** and, if needed, **continuously and in real-time** ✓ Make data available to **data recipients** in a way that is **fair, reasonable and non-discriminatory** ✓ Make data available to public **sector bodies and EU bodies** on the basis of **exceptional need**

Regulatory intersection

How do the EU's cyber and digital laws intersect?

*The analyzed legislation requires entities to **demonstrate compliance with ICT security requirements.***

***NIS2** provides that Member States **may require** essential and important entities to use particular ICT products, ICT services and ICT processes, either developed by the entity or procured from third parties, that are **certified under European cybersecurity certification schemes** adopted under the **Cybersecurity Act**. In the absence of appropriate European cybersecurity certification schemes, Member States shall require entities to comply with **relevant European and international standards** (e.g., **upcoming AI standards** defined by CEN/CENELEC and **standardization of cybersecurity requirements under CRA**). Entities shall **oversee the compliance with ICT security requirements by providers** as part of their third-party risk management obligations*

*The analyzed legislation, without prejudice to the overall compliance with **data protection obligations under the GDPR**, requires entities to comply with **additional subject-specific obligations** (e.g., ensuring that **input data is relevant and sufficiently representative** under the **AI Act**, **making data available** under the Data Act)*

The use case is based on a set of assumptions, as per slide 56, that may not account for all possible scenarios: [1]Manufacturer; [2]Important entity of a type referred to in Annex II; [3]Manufacturer; [4]Deployer of a high-risk AI system; [5]Data holder

Legend: Cybersecurity | Platform economy | AI & Data | Digital finance | Digital identity

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Manufacturing & Consumer – Use Case 2 (1/4)

The Manufacturing & Consumer's use case 2 provides an illustrative snapshot of how a Manufacturer of motor vehicles, trailers and semitrailers is impacted by the identified EU digital and cyber legislation and is based on a set of assumptions that may not account for all possible scenarios

Sector

Manufacturing & Consumer. This sector includes public and private entities operating in the following industries: **manufacturing** of **medical devices**, **computer**, **electronic** and **optical products**, **electrical equipment**, **machinery**, **motor vehicles**, trailers and semi-trailers, other **transportation equipment**, **manufacturing** of **consumer products.**

Identification of an entity within the sector

Entity

Manufacturer of motor vehicles, trailers and semitrailers

Definition of the assumptions to build an illustrative use case

Assumptions

Since each legislation imposes specific requirements on entities based on their roles, it is assumed that the Manufacturer of motor vehicles, trailers and semitrailers, under the selected legislation, acts as:

NIS2	RED	AI Act	Data Act
Important entity	Manufacturer	Provider of a high-risk AI system	Data holder
An entity referred to in Annex II "Other Critical Sectors".	Any person or company that makes radio equipment or has it designed or produced, and then sells or distributes it under their own name or brand.	Any person, organization, or public entity that either creates an AI system or model, or has one created, and then offers it for use or sale under their own name or brand. This can be done whether they charge for it or offer it for free.	A person or organization that has the right or responsibility, under this regulation or other relevant laws, to use and share data. This can include product or service data that they have gathered or created while providing a service, if agreed upon in a contract.

*NACE Rev. 2. Statistical classification of economic activities in the European Community: https://ec.europa.eu/eurostat/documents/3859598/5902521/KS-RA-07-015-EN.PDF

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Manufacturing & Consumer – Use Case 2 (2/4)

Manufacturer of motor vehicles, trailers and semitrailers

Obligations

	NIS2[1]	RED[2]	AI Act[3]	Data Act[4]
Governance Measures	✓ Establish appropriate and proportionate **governance measures**, i.e. accountability of management bodies for cybersecurity risk management measures ✓ Establish appropriate and proportionate **organizational measures** based on an **all-hazards approach** to manage cybersecurity related **risks**	✓ Implement a quality system which, inter alia, describes the **quality objectives** and the **organizational structure**, **responsibilities and powers of the management** with regard to design and product quality	✓ Put in place and document a **quality management system**, including an accountability framework detailing **roles** and **responsibilities** regarding high-risk AI systems ✓ **Assign human oversight** to natural persons who have the necessary competence, training and authority ✓ Ensure the staff has **adequate AI literacy** ✓ Enforce the **conformity assessment procedure** for high-risk AI systems ✓ Register AI systems and themselves in the EU and, if needed, national **database**	x *Not covered*
Risk Management & Technical Standards	✓ Establish appropriate and proportionate **technical and operational measures to manage cybersecurity related risks**, e.g., adopt adequate policies, including business continuity and disaster recovery, third-party and supply chain security, ensure security in network and information systems acquisition, development and maintenance, adopt basic cyber hygiene practices and cybersecurity training, use of multi-factor authentication or continuous authentication solutions	✓ Ensure that **radio equipment complies with essential security requirements**	✓ Establish, implement, document, and maintain a **risk management system**, namely continuous **iterative process planned and run throughout the entire lifecycle of a high-risk AI system**, to evaluate risks possibly arising ✓ Perform a **fundamental rights impact assessment (FRIA)** for high-risk AI systems before deployment ✓ **Establish and document a post-market monitoring system** that collects, documents and analyses relevant data on the performance of high-risk AI systems throughout their lifetime, including possible risks	✓ ***May*** apply appropriate **technical protection measures**, including smart contracts and encryption, to prevent **unauthorized access to data**, including metadata, and to ensure compliance with data sharing obligations and with the agreed contractual terms for making data available

Regulatory intersection

How do the EU's cyber and digital laws intersect?

*The analyzed legislation requires entities to **review their internal security governance systems** (e.g., cyber/IT security and physical security convergence based on an all-hazard approach), strengthen **accountability of management bodies**, and establish clear **roles and responsibilities** for overseeing and managing ICT-related risks.*

*Being a horizontal legislation, **NIS2** introduces a general obligation to set a **clear and technology-agnostic risk governance framework**, while subject-specific legislation – such as RED and AI Act – introduces **vertical requirements**.*

*Therefore, **compliance** to, respectively, to radio equipment and high-risk AI systems **vertical requirements contributes** to the fulfillment of **NIS2 overall governance** obligations*

*The analyzed legislation requires entities to set up an **ICT-related risk management framework.***

*As a horizontal legislation, NIS2 introduces a broad obligation to set up a **comprehensive, documented and regularly updated risk management framework**, namely strategies, policies, procedures, ICT protocols and tools to prevent, detect and manage ICT-related risks.*

*With specific regard of high-risk AI systems, **providers** shall establish a **risk management system** throughout the entire lifecycle of a high-risk AI system and **monitor the use** of such systems.*

*Moreover, entities shall comply with **essential security requirements** envisaged by the RED Directive (and Delegated Regulation).*

The use case is based on a set of assumptions, as per slide 60, that may not account for all possible scenarios: [1]Important entity of a type referred to in Annex II; [2]Manufacturer; [3]Provider of a high-risk AI system; [4]Data holder

Legend: Cybersecurity | Platform economy | AI & Data | Digital finance | Digital identity

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Manufacturing & Consumer – Use Case 2 (3/4)

Manufacturer of motor vehicles, trailers and semitrailers

Obligations

	NIS2[1]	RED[2]	AI Act[3]	Data Act[4]
Vulnerability Management	✓ Establish appropriate and proportionate **technical** and **operational measures** to **manage vulnerabilities** and **report** them to the **national CSIRT** an, where needed, to **service recipients** ✓ Take into account **vulnerabilities** specific to **direct suppliers** and **service providers** and the overall **quality of their products** and cybersecurity **practices**	x *Not covered*	✓ Implement **measures to prevent, detect, respond to, resolve and control for attacks trying to manipulate the training data set**, or pre-trained components used in training, inputs designed to cause the AI model to make a mistake, confidentiality attacks or model flaws	x *Not covered*
Incident Management	✓ Establish appropriate and proportionate **technical** and **operational** measures for **incident handling** ✓ Establish **business continuity** measures, such as backup management and **disaster recovery**, and **crisis management** ✓ Notify to **national CSIRT**, or **competent authority**, any **incident** that has a **significant impact** on the provision of the operator's services	x *Not covered*	✓ **Notify** to **market surveillance authorities** the occurrence of **serious incidents** that directly or indirectly leads to the death of, or serious harm to, a person, a serious disruption of the management or operation of critical infrastructure, a violation of fundamental rights	✓ In case of **emergencies** and **major disasters**, such as **major cybersecurity incidents**, data holders shall **make data available to public sector bodies**, the Commission, the European Central Bank or Union bodies upon their request

Regulatory intersection

How do the EU's cyber and digital laws intersect?

*The analyzed legislation requires entities to implement **appropriate measures** and **processes** to **manage ICT system vulnerabilities**, such as **periodic vulnerability assessment and penetration testing**, as well as to **record and mitigate** such vulnerabilities either directly or with the involvement of ICT providers.*

*With regard to **AI systems**, providers need to **comply with strict monitoring obligations**, both ante- and post-market. This contributes to the overall NIS2 compliance.*

*Finally, considering **reporting obligations**, Member States are expected to **provide single entry points** at national level to alleviate administrative burden on entities*

*The analyzed legislation requires entities to set up appropriate measures for **ICT incident management and reporting**. NIS2 sets a general obligation to **manage incidents throughout their lifecycle** according to recognized standards and frameworks, covering analogous product-specific obligations.*

*With regard to **incident reporting obligations under NIS2**, Member States are expected to **provide single entry points** at national level to alleviate administrative burden. The **AI Act** requires providers to notify **market surveillance authorities** of serious incidents. However, **it is likely that such authorities will coincide with the single-entry points** designated under NIS2, in order to streamline reporting obligations*

*Finally, in case of **major cybersecurity incidents**, entities shall **make data available** to **public sector bodies** and **Union bodies**.*

The use case is based on a set of assumptions, as per slide 60, that may not account for all possible scenarios: [1]Important entity of a type referred to in Annex II; [2]Manufacturer; [3]Provider of a high-risk AI system; [4]Data holder

Legend: Cybersecurity | Platform economy | AI & Data | Digital finance | Digital identity

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Manufacturing & Consumer – Use Case 2 (4/4)

Manufacturer of motor vehicles, trailers and semitrailers

Obligations

	NIS2[1]	RED[2]	AI Act[3]	Data Act[4]
ICT Security Compliance & Certification	✓ ***May*** be required to use **IT/OT products**, **services** and **processes**, **developed** by the operator or **procured** from third parties, that are **certified** under **European cybersecurity certification schemes** adopted under the Cybersecurity Act, in order to demonstrate compliance with cybersecurity risk management measures	✓ Ensure that **radio equipment** comply with essential requirements set out in Article 3, RED and Delegate Regulation 2022/30 ✓ Provide the Member States and the Commission with information on the compliance of **intended combinations of radio equipment and software** resulting from a **conformity assessment** in the form of a statement of compliance (EU declaration of conformity)	✓ Perform a **conformity assessment** to demonstrate compliance with **all requirements for high-risk AI systems,** including **cybersecurity requirements** ✓ Draw up **technical documentation** to demonstrate compliance ✓ Affix the **CE marking**	x *Not covered*
Data Governance & Management	✓ Comply with **fundamental data protection obligations**, including the obligation to carry out a Data Protection Impact Assessment (**DPIA**), as per the GDPR	✓ Radio equipment has to incorporate safeguards to ensure that the **personal data and privacy** of the user and of the subscriber **are protected**	✓ Ensure that input data is **relevant and sufficiently representative** in view of the intended purpose of the high-risk AI system ✓ Comply with obligation to carry out a **data protection impact assessment** as set out by Regulation 2016/679 (GDPR)	✓ Make data available to users or to a party acting on user's behalf **easily, securely, free of charge, in a comprehensive, structured, commonly used and machine-readable format** and, if needed, **continuously and in real-time** ✓ Make data available to **data recipients** in a way that is **fair, reasonable and non-discriminatory** ✓ Make data available to public **sector bodies and EU bodies** on the basis of **exceptional need**

Regulatory intersection

How do the EU's cyber and digital laws intersect?

*The analyzed legislation requires entities to **demonstrate compliance with security requirements**.*

*NIS2 provides that Member States **may require** essential and important entities to use particular IT/OT products, services and processes, either developed by the entity or procured from third parties, that are **certified under European cybersecurity certification schemes** adopted under the Cybersecurity Act. In the absence of appropriate European cybersecurity certification schemes, Member States shall require entities to comply with **relevant European and international standards** (e.g., **upcoming AI standards** defined by CEN/CENELEC). Entities shall **oversee the compliance with ICT security requirements by providers** as part of their third-party risk management obligations*

*The analyzed legislation, without prejudice to the overall compliance with **data protection obligations under the GDPR**, requires entities to comply with **additional subject-specific obligations** (e.g., ensuring that **input data is relevant and sufficiently representative** under the **AI Act**, **making data available** under the Data Act)*

The use case is based on a set of assumptions, as per slide 60, that may not account for all possible scenarios: [1]Important entity of a type referred to in Annex II; [2]Manufacturer; [3]Provider of a high-risk AI system; [4]Data holder

Legend: Cybersecurity | Platform economy | AI & Data | Digital finance | Digital identity

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Technology, Media & Telecommunications – Use Case 1 (1/4)

The Government & Public Services' use case 1 provides an illustrative snapshot of how a Provider of public electronic communications networks is impacted by the identified EU digital and cyber legislation and is based on a set of assumptions that may not account for all possible scenarios

Sector

Technology, Media & Telecommunications. This key sector includes public and private entities operating in the following industries: digital infrastructure services, ICT service management, intermediary services, core platform services, qualified / non-qualified trust services, telecommunications, network connectivity.

Identification of an entity within the sector

Entity

Provider of public electronic communications networks*

Definition of the assumptions to build an illustrative use case

Assumptions

Since each legislation imposes specific requirements on entities based on their roles, it is assumed that the Provider of public electronic communications networks, under the selected legislation, acts as:

CRA	NIS2	RED	AI Act	Data Act	eIDAS
Manufacturer	Essential entity	Manufacturer	Deployer of a high-risk AI system	Data holder	Trust service provider
An entity that creates or produces products with digital components, or has them made, and then sells or distributes them under their own name or brand, whether for payment, profit, or for free.	An entity referred to in Annex I "Sectors of High Criticality," which exceeds the ceilings for medium-sized enterprises.	Any person or company that makes radio equipment or has it designed or produced, and then sells or distributes it under their own name or brand.	Any individual, organization, government body, agency, or entity using an AI system under its control, unless the AI system is being used for personal, non-professional purposes.	A person or organization that has the right or responsibility, under this regulation or other relevant laws, to use and share data. This can include product or service data that they have gathered or created while providing a service, if agreed upon in a contract.	Any individual or organization that offers trust services, whether they are certified as qualified or not.

*Depending on the services provided, network providers might obtain banking licenses and act as banking institutions, thus falling under DORA requirements

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Technology, Media & Telecommunications – Use Case 1 (2/4)

Provider of public electronic communications networks

Obligations

	CRA[1]	NIS2[2]	RED[3]	AI Act[4]	Data Act[5]	eIDAS[6]
Governance Measures	✓ Establish and document a **quality system** that describes, inter alia, the **organizational structure, responsibilities and powers of the management** with regard to design, development, product quality and vulnerability handling of a product with digital elements	✓ Establish appropriate and proportionate **governance measures**, i.e. accountability of management bodies for cybersecurity risk management measures ✓ Establish appropriate and proportionate **organizational measures** based on an **all-hazards approach** to manage cybersecurity related **risks**	✓ Implement a **quality system** which, inter alia, describes the **quality objectives** and the **organizational structure, responsibilities and powers** of the management with regard to design and product quality	✓ Take appropriate **organizational measures** to ensure that the use of **high-risk AI systems** is in accordance with the instructions for the use of such system ✓ Ensure the staff has **adequate AI literacy** ✓ **Assign human oversight to natural persons** who have the necessary competence, training and authority, as well as the necessary support	x *Not covered*	✓ Take appropriate **organizational measures** to manage risks posed to the security of the trust services provided ✓ Employ **staff** and, if applicable, **subcontractors** who possess the necessary **expertise, reliability, experience, and qualifications** and who have received appropriate training regarding **security and personal data protection rules**
Risk Management & Technical Standards	✓ Ensure that the **product** with digital elements has been **designed**, **developed** and **produced** in accordance with the **essential cybersecurity requirements,** of both **products** and **processes**, i.e. undertake an assessment of the **cybersecurity risks** associated with a product with digital elements and take the outcome of that assessment during the product's lifecycle	✓ Establish appropriate and proportionate **technical and operational measures to manage cybersecurity related risks**, e.g., adopt adequate policies, including business continuity and disaster recovery, third-party and supply chain security, ensure security in network and information systems acquisition, development and maintenance	✓ Ensure that **radio equipment complies with essential security requirements**	✓ Take appropriate **technical measures** to ensure that the use of **high-risk AI systems** is in accordance with the instructions for use ✓ Perform a **FRIA** for high-risk AI systems before deployment ✓ **Monitor** the **operation of the high-risk AI system** based on the instructions for use and share relevant data with providers and **inform** the **provider or distributor** and relevant **market surveillance authority**, and **suspend the use** of that system if it poses **unacceptable risk**	✓ ***May*** apply appropriate **technical protection measures**, including smart contracts and encryption, to prevent **unauthorised access to data**, including metadata, and to ensure compliance with data sharing obligations and with the agreed contractual terms for making data available	✓ Take appropriate **technical and organizational measures to manage risks** posed to the security of the trust services provided ✓ Use **trustworthy systems and products** that are protected against modification and ensure the **technical security and reliability** of the processes supported by them ✓ Comply with service-specific security **requirements** (e.g., ICT security for electronic signatures)

Regulatory intersection

How do the EU's cyber and digital laws intersect?

*The analyzed legislation requires entities to **review their internal governance systems** in view to establishing clear **roles and responsibilities** for overseeing and managing ICT-related risks. Being a horizontal legislation, NIS2 introduces a general obligation to set a **clear and technology-agnostic risk governance framework**, while subject-specific legislation – such as CRA, RED, AI Act, and eIDAS – introduces **vertical requirements** the compliance with which contributes to the overall fulfilment of governance obligations*

*The analyzed legislation requires entities to set up an **ICT-related risk management framework.***

*As a horizontal legislation, NIS2 introduces a broad obligation to set up a **comprehensive, documented and regularly updated risk management framework**, including strategies, policies, procedures, ICT protocols and tools to prevent, detect and manage ICT-related risks.*

*Other subject-specific **risk management obligations** (e.g., under the CRA, RED, AI Act, Data Act, and eIDAS) constitute further specifications of the overall risk management framework that entities need to implement. Hence, compliance with the latter contributes to the overall NIS2 compliance*

The use case is based on a set of assumptions, as per slide 64, that may not account for all possible scenarios: [1] Manufacturer [2] Essential entity of a type referred to in Annex I; [3] Manufacturer; [4] Deployer of a high-risk AI system; [5] Data holder; [6] Trust service provider

Legend: Cybersecurity | Platform economy | AI & Data | Digital finance | Digital identity

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Technology, Media & Telecommunications – Use Case 1 (3/4)

Provider of public electronic communications networks

Obligations

	CRA[1]	NIS2[2]	RED[3]	AI Act[4]	Data Act[5]	eIDAS[6]
Vulnerability Management	✓ Ensure that the **product** with digital elements has been **designed**, **developed** and **produced** in accordance with **vulnerability handling requirements**, i.e. establish appropriate vulnerability disclosure policies ✓ **Notify** any **actively exploited vulnerability** contained in the product with digital elements to the national **CSIRT** designated as coordinator and to **ENISA** via the **single reporting platform**	✓ Establish appropriate and proportionate **technical** and **operational measures** to **manage vulnerabilities** and **report** them to the **national CSIRT** an, where needed, to **service recipients** ✓ Take into account **vulnerabilities** specific to **direct suppliers** and **service providers** and the overall **quality of their products** and cybersecurity **practices**	x *Not covered*	x *Not covered*	x *Not covered*	✓ Perform a regular 2-year **vulnerability assessment to maintain the certification of conformity** for **qualified electronic signature creation devices**
Incident Management	✓ Ensure that the **product** with digital elements has been **designed**, **developed** and **produced** in accordance with essential cybersecurity requirements **to prevent incidents and minimize their impact** ✓ **Notify** any **severe incident** having an impact on the security of the product with digital elements to the **CSIRT** designated as coordinator and to **ENISA** via the **single reporting platform**	✓ Establish appropriate and proportionate **technical** and **operational** measures for **incident handling** ✓ Establish **business continuity** measures, such as backup management and **disaster recovery**, and **crisis management** ✓ Notify to **national CSIRT**, or **competent authority**, any **incident** that has a **significant impact** on the provision of the operator's services	x *Not covered*	✓ **Monitor** the **operation of the high-risk AI system** on the basis of the instructions for use and share relevant data with providers within their post-market monitoring activities, including data regarding any **discovered serious incident** ✓ **Inform** first the **provider**, and then the **importer** or **distributor** and the relevant **market surveillance authorities** in case of a **serious incident** as defined in Article 3(49)	✓ In case of **emergencies** and **major disasters**, such as **major cybersecurity incidents**, data holders shall **make data available to public sector bodies**, the Commission, the European Central Bank or Union bodies upon their request	✓ Take appropriate technical and **organizational measures** to prevent and minimize the impact of **security incidents** ✓ Notify **supervisory authority** or other relevant **bodies** within 24h of any **breach of security or loss of integrity** that has a significant impact on the trust service provided or on personal data ✓ Notify the **legal or natural person** to whom the service is provided

Regulatory intersection

How do the EU's cyber and digital laws intersect?

*The analyzed legislation requires entities to implement **appropriate measures** and processes to **manage ICT system vulnerabilities**, such as **periodic vulnerability assessment and penetration testing**, as well as to **record and mitigate** such vulnerabilities either directly or with the involvement of ICT providers.*

*With regard to **AI systems**, **deployers cannot directly test the infrastructure** of the AI system. It is likely that they will oversee the overall security of the AI system through their **overall third-party risk management framework** (e.g. reviewing supply chains and negotiating specific contractual clauses)*

*The analyzed legislation requires entities to set up appropriate measures for **ICT incident reporting** and **handling**. While NIS2 outlines measures for the notification of **ICT significant incidents** to national CSIRTs, or competent authorities, the **CRA** and **eIDAS** outline, respectively, measures for the notification of **severe incidents** to **CSIRTs** and breach of security or loss of integrity to supervisory authorities. Furthermore, reporting obligations set out in **eIDAS** have to be considered **complementary** to those outlined in **NIS2**. The legislation aims to **simplify** and **streamline** reporting procedures by encouraging the establishment of national **single-entry points** for the fulfillment of reporting requirements. Currently, the **AI Act** falls **outside such requirements** and envisages notification procedures towards **market surveillance authorities.** However, such authorities are **encouraged to correspond to single entry points.** Finally, in case of **major cybersecurity incidents**, entities shall **make data available** to **public sector bodies** and **Union bodies**.*

The use case is based on a set of assumptions, as per slide 64, that may not account for all possible scenarios: [1] Manufacturer [2]Essential entity of a type referred to in Annex I; [3]Manufacturer; [4] Deployer of a high-risk AI system; [5]Data holder; [6] Trust service provider

Legend: Cybersecurity | Platform economy | AI & Data | Digital finance | Digital identity

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Technology, Media & Telecommunications – Use Case 1 (4/4)

Provider of public electronic communications networks

Obligations

	CRA[1]	NIS2[2]	RED[3]	AI Act[4]	Data Act[5]	eIDAS[6]
ICT Security Compliance & Certification	✓ Perform a **cybersecurity conformity assessment** of **products** and **processes** to demonstrate compliance with essential cybersecurity requirements ✓ Draw up **technical documentation** to demonstrate compliance ✓ Affix the **CE marking** ✓ Identify **"important"** or **"critical" products** with digital elements that are subject to **additional controls** and **conformity assessment procedures**	✓ ***May*** be required to use **IT/OT products**, **services** and **processes**, **developed** by the operator or **procured** from third parties, that are **certified** under **European cybersecurity certification schemes** adopted under the Cybersecurity Act, in order to demonstrate compliance with cybersecurity risk management measures	✓ Provide the Member States and the Commission with information on the compliance of **intended combinations of radio equipment and software** resulting from a connformity assessment in the form of a statement of compliance (EU declaration of conformity) ✓ Affix the **CE marking**	x *Not covered*	x *Not covered*	✓ Carry out an **audit** by a conformity assessment body at least every 24 months and **submit the resulting conformity assessment report** to competent supervisory authorities ✓ Rely on **cybersecuirty certification schemes** to demonstrate compliance of European Digital Identity Wallets
Data Governance & Management	✓ **Safeguard** the Confidentiality, Integrity and Availability (**CIA**) of processed data ✓ **Ensure** the **possibility** for **users** to securely and easily **remove** on a permanent basis **all data and settings** ✓ Ensure **data portability**	✓ Comply with **fundamental data protection obligations**, including the obligation to carry out a Data Protection Impact Assessment (**DPIA**), as per the GDPR	✓ Radio equipment must incorporate safeguards to ensure that the **personal data and privacy** of the user and of the subscriber **are protected**	✓ Ensure that **input data** is **relevant** and **sufficiently representative** in view of the intended purpose of the high-risk AI system, to the extent the deployer exercises control over the input data ✓ **Keep the logs**, to the extent that they are under the deployer's control, **automatically generated** by the high-risk AI system for a period appropriate to the intended purpose of the high-risk AI system	✓ Make data available to users or to a party acting on user's behalf **easily, securely, free of charge, in a comprehensive, structured, commonly used and machine-readable format** and, if needed, **continuously and in real-time** ✓ Make data available to **data recipients** in a way that is **fair, reasonable and non-discriminatory** ✓ Make data available to public **sector bodies and EU bodies** on the basis of **exceptional need**	✓ Use **trustworthy systems** to safeguard **confidentiality, integrity, and availability** of data ✓ Take appropriate **measures** against **forgery and theft of data** ✓ Comply with fundamental data obligations outlined in Regulation 2016/679 (GDPR)

Regulatory intersection

How do the EU's cyber and digital laws intersect?

*The analyzed legislation requires entities to **demonstrate compliance with ICT security requirements.***

*NIS2 provides that Member States **may require** essential and important entities to use particular ICT products, ICT services and ICT processes, either developed by the entity or procured from third parties, that are **certified under European cybersecurity certification schemes** adopted under the Cybersecurity Act. In the absence of appropriate European cybersecurity certification schemes, Member States shall require entities to comply with **relevant European and international standards** (e.g., **upcoming AI standards** defined by CEN/CENELEC and **standardization of cybersecurity requirements under CRA**). Entities shall **oversee the compliance with ICT security requirements by providers** as part of their third-party risk management obligations. Finally, **CRA requirements** are aligned to requirements of the **RED Delegated Regulation***

*The analyzed legislation, without prejudice to the overall compliance with **data protection obligations under the GDPR**, requires entities to comply with **additional subject-specific obligations** (e.g., ensuring that input data is relevant and sufficiently representative under the AI Act, making data available under the Data Act, and taking appropriate measures against forgery and theft of data under eIDAS)*

The use case is based on a set of assumptions, as per slide 64, that may not account for all possible scenarios: [1] Manufacturer [2] Essential entity of a type referred to in Annex I; [3] Manufacturer; [4] Deployer of a high-risk AI system; [5] Data holder; [6] Trust service provider

Legend: Cybersecurity | Platform economy | AI & Data | Digital finance | Digital identity

Annex A | Level of penalties (1/2)

Non-compliance with the identified digital regulations can lead to a wide range of penalties depending on the total worldwide turnover or the average daily global turnover of the entities subject to the obligations

- **DMA** (repetition of non-compliance within 8 years of a non-compliance decision by the EC): 20%
- **MiCA** (insider dealing, unlawful disclosure of inside information, market manipulation): 15% (of the total annual turnover of the legal person)
- **MiCA** (admission to stablecoin trading, obligations of stablecoin issuers, recovery and redemption plans; requirements to be fulfilled by all issuers of e-money tokens (inter alia, marketing)): 12.5%
- **DMA** non-compliance decision by the EC (failure to comply with obligations, ordered remedies/ interim measures, legal commitments): 10%
- **AI Act** (unacceptable use cases): 7%
- **DSA** (general failure to comply): 6%
- **DSA** (periodic penalties): 5%
- **MiCA** (authorization of crypto-asset service providers and obligations for all and specific crypto-asset service providers (conduct, prudential requirements, governance, safekeeping, outsourcing, etc.)): 5%
- **DMA** (daily fines for non-compliance with gatekeeper-specific measures adopted by the EC (Art. 8(2)), information obligations, inspections, interim measures and legal commitments): 5%*
- **MiCA** (admission to cryptocurrency trading): 3% (of the total annual turnover of the legal person)
- **AI Act** (failure to comply with obligations of high-risk AI and GPAI models): 3%
- **CRA** (non-compliance with essential cybersecurity requirements): 2.5%
- **CRA** (various importers'/ distributors duties etc.): 2%
- **MiCA** (failure to respect rules regarding publication of inside information): 2%
- **AI Act** (offences related to response to authorities' request for information): 1%
- **DSA, CRA, DMA** (offences related to publication of information/response to authorities' request for information): 1%
- **eIDAS2** (all infringements): 1%

Legend

- 15% or more
- 10.01 – 14.99 %
- 5.01 – 10 %
- 1.01 – 5,00 %
- 0 – 1 %
- % of total worldwide turnover in the preceding financial year
- % of the average daily worldwide turnover in the preceding financial year
- % of the company's total annual turnover from the most recent approved financial statements

(*) Subject to a 5-year limitation period
(**) DSA only defines maximum penalties; Member States remain responsible for setting penalties. Hence, differences between Member States may arise

Annex A | Level of penalties (2/2)

Non-compliance with the identified digital regulations can lead to a wide range of penalties depending on the total worldwide turnover or the average daily global turnover of the entities subject to the obligations

Maximum penalties

AI Act (Unacceptable use cases): €35M

AI Act (Failure to comply with obligations of high-risk AI and GPAI models): €15M

CRA (non-compliance with essential cybersecurity requirements): €15M

MiCA (insider dealing, unlawful disclosure of inside information, market manipulation): € 15M

CRA (various importers'/ distributors' duties etc.): € 10M

AI Act (Incorrect, incomplete, misleading response to request for information): €7.5M

CRA (information supply offences): € 5M

MiCA: (admission to cryptocurrency and stablecoin trading, obligations of stablecoin issuers, asset reserves, recovery and redemption plans, requirements for all e-money issuers, marketing, authorisation of crypto-asset service providers, obligations for all and specific crypto-asset service providers (conduct, prudential requirements, governance, safekeeping, outsourcing, etc.): € 5M

eIDAS2 (all infringements): € 5M

MiCA (failure to respect rules regarding publication of inside information): € 2.5M

Legend

- € 35M and above
- € 10 – 35M
- € 5 - 10M
- € 0 - 5M

Note: when deciding between percentage of turnover or a fixed sum, in case of the AI Act, the principle of "whichever is greater" applies, unless the perpetrator is an SME (to which "whichever is lower" applies).

In case of the CRA and eIDAS2, the principle of "whichever is greater" applies.

Annex B | References (1/2)

List of published legislation and proposals leveraged to develop the EU Policy Centre Playbook

Legislation published on the EU Official Journal

- Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006L0042
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- Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0910
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745
- Commission Delegated Regulation (EU) 2022/30 of 29 October 2021 supplementing Directive 2014/53/EU of the European Parliament and of the Council with regard to the application of the essential requirements referred to in Article 3(3), points (d), (e) and (f), of that Directive. Available at: https://eur-lex.europa.eu/eli/reg_del/2022/30/oj
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- Directive (EU) 2022/2380 of the European Parliament and of the Council of 23 November 2022 amending Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2022.315.01.0030.01.ENG&toc=OJ%3AL%3A2022%3A315%3ATOC
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- Regulation (EU) 2022/2554 of the European Parliament and of the Council of 14 December 2022 on digital operational resilience for the financial sector and amending Regulations (EC) No 1060/2009, (EU) No 648/2012, (EU) No 600/2014, (EU) No 909/2014 and (EU) 2016/1011. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R2554&qid=1712306799442
- Regulation (EU) 2024/903 of the European Parliament and of the Council of 13 March 2024 laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202400903

Annex B | References (2/2)

List of published legislation and proposals leveraged to develop the EU Policy Centre Playbook

- Directive (EU) 2022/2555 of the European Parliament and of the Council of 14 December 2022 on measures for a high common level of cybersecurity across the Union, amending Regulation (EU) No 910/2014 and Directive (EU) 2018/1972, and repealing Directive (EU) 2016/1148 (NIS 2 Directive). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022L2555&qid=1712306799442
- Regulation (EU) 2023/1114 of the European Parliament and of the Council of 31 May 2023 on markets in crypto-assets, and amending Regulations (EU) No 1093/2010 and (EU) No 1095/2010 and Directives 2013/36/EU and (EU) 2019/1937. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023R1114&qid=1712307150661
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- Commission Delegated Regulation (EU) 2023/1717 of 27 June 2023 amending Directive 2014/53/EU of the European Parliament and of the Council as regards the technical specifications for the charging receptacle and charging communication protocol for all the categories or classes of radio equipment capable of being recharged by means of wired charging. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2023.223.01.0001.01.ENG
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- Regulation (EU) 2024/1183 of the European Parliament and of the Council of 11 April 2024 amending Regulation (EU) No 910/2014 as regards establishing the European Digital Identity Framework. Available at: https://eur-lex.europa.eu/eli/reg/2024/1183/oj
- Regulation of the European Parliament and of the Council on Horizontal Cybersecurity Requirements for Products with Digital Elements and Amending Regulations (Eu) No 168/2013 And (Eu) 2019/1020 And Directive (Eu) 2020/1828 (Cyber Resilience Act). Available at: https://data.consilium.europa.eu/doc/document/PE-100-2023-REV-1/en/pdf

Proposals

- Proposal for a regulation of the European Parliament and of the Council laying down measures to strengthen solidarity and capacities in the Union to detect, prepare for and respond to cybersecurity threats and incidents, and amending Regulation (EU) 2021/694. Available at: https://www.consilium.europa.eu/media/69093/st16996-en23.pdf
- Proposal for a Regulation on the European Health Data Space – Compromise text (March 2024). Available at: https://www.consilium.europa.eu/media/70909/st07553-en24.pdf

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