

# ANIA Exploring Digital Regulation

**Focus on** artificial intelligence, digital  
finance and cybersecurity



Associazione Nazionale  
fra le Imprese Assicuratrici

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In September 2020, in the **State of the Union Address** at the European Parliament Plenary, EU Commission's President von der Layen stressed the need for a common plan for digital Europe with clearly defined goals for **2030**: the so-called "**Europe's Digital Decade**".

This led to the issuance of the so-called "**2030 Digital Compass**", by means of which the EU Commission identified the cardinal points that shall drive European digital transformation.

In this context, the European regulator - also prompted by the spread of the **pandemic**, which highlighted the key role of modern technologies in all sectors of activity and for people's welfare in general - has already undertaken several **legislative and non-legislative initiatives towards digitalisation** in order to secure European digital sovereignty and accelerate the process for making Europe not dependent on others in this field.

As a result, we are currently experiencing the development of several **new regulatory frameworks** that are capable to affect, under different perspectives, the activity of market players, including **insurance companies**.

Examples of this phenomenon are, among others, the European Strategies on **Artificial Intelligence, Digital Finance, Data, Digital Services** and **Cybersecurity**.

Such a disruptive regulatory evolution brings ANIA to launch a new series of newsletter called "ANIA Exploring Digital Transformation", whose goal is to provide short hints on the most significant developments along the path towards digital transformation and the relevant implications for the insurance market.

The newsletters will be issued on a regular basis, in a one-page format, and will be collected in a single volume to form a practical - and easy to use - reference guide.

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# The European Strategy on AI: Coordinated Plan on Artificial Intelligence

1 APRIL, 14  
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Artificial Intelligence (“AI”) is deemed to be a set of technologies of **strategic relevance** for the European Union. It is considered as a tool to increase productivity across all economic sectors, create new markets and employment opportunities, build up greater resilience to future shocks and help recovering from previous ones, as well as an instrument to enhance opportunities for people in need, boost education and skills, and contribute to the objectives of the EU security strategy.

On the other hand, the use of AI also creates a number of specific **high risks** that the existing legislation is not able to address properly. This is because algorithms underlying AI are often characterized by **opacity** that may compromise the possibility to reconstruct the decision-making process followed by the AI system and the results achieved. This implies difficulties in assessing and proving the correctness of the decisions taken as well as identifying any potential liabilities. Also, **poor training and design** of AI systems may undermine privacy and non-discrimination.

In light of the foregoing, in April 2018 the **European Union launched a European strategy on AI** aimed at making the EU a world-class hub for AI, while ensuring that AI is human-centric and trustworthy. In December 2018 the **first coordinated plan on AI** was published, consisting in a joint commitment between Member States to foster the development and use of AI in Europe and to coordinate European and national efforts on AI.

Later, in April 2019, the **High-Level Expert Group on Artificial Intelligence** (HLEG) developed the **Guidelines for Trustworthy AI** and, in July 2020, an **Assessment List for Trustworthy AI** (ALTAI). Reference shall be made also to the EU Commission’s **White Paper on AI** published in February 2020, which proposed a number of measures and policy options (including the amendment of the existing legal framework) in order to promote the uptake of AI and address the risks associated with certain uses of this new technology.

Moreover, strengthening Europe’s AI capabilities is also a key element of the wider strategy defined in the **2030 Digital Compass** published in March 2021.

The described path – and the need to take into account the constant evolution of the technological, economic and policy context on AI – led to the issuance, in April 2021, of a **revised Coordinated Plan on AI**, that was published together with a **proposal for a regulatory framework on AI**.

The revised Coordinated Plan on AI identifies four key sets of policy objectives on how the EU Commission, together with the Member States and private actors, can achieve the opportunities offered by AI technologies (including investing in data spaces and computing resources, fund AI testing and experimentation facilities, etc.). Among such initiatives, particular attention shall be paid to that of **developing a policy framework to ensure trust in AI system**, which focuses on three interrelated issues: issues of safety and fundamental rights, issues of liability of AI and revision of the existing sectoral safety legislation when necessary.

Monitoring the evolution of such initiatives seems crucial also for the **insurance sector**, considering the take-up of AI in all the areas of the insurance value chain.

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# Proposal for an Artificial Intelligence Act

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On 21 April, 2021, the European Commission issued a proposal for a regulation providing a new set of rules and actions aimed at making the EU a global leader in the development of secure, trustworthy and ethical artificial intelligence (the so-called “**Artificial Intelligence Act**” - **COM(2021) 206 final**). The AI Act aims at laying down a uniform legal framework on artificial intelligence matters to foster the development, use and uptake of AI in the internal market while ensuring a high level of protection of public interests, such as health and safety and the protection of fundamental rights, as recognised and protected by EU law.

In particular, the proposal at hand sets forth a robust and flexible **legal framework for trustworthy AI**, for the purposes of giving people and other users the confidence to embrace AI-based solutions, while encouraging businesses to develop them. In order to achieve such objectives, the proposal adopts a balanced and proportionate horizontal regulatory approach to AI that is limited to the **minimum necessary requirements** to address the risks and problems linked to AI, without unduly constraining or hindering technological development.

More specifically, the proposal follows a **risk-based approach** and provides for regulatory burdens only when AI systems are likely to pose high risks to fundamental rights and safety. In this perspective, the proposal distinguishes between **high-risk AI systems** and non-high-risk AI systems. Only the first ones will have to comply with a set of horizontal **mandatory requirements** for trustworthy AI (e.g., the requirements of high quality data) and follow specific **conformity assessment procedures** before those systems can be placed on the Union market.

Differently, for **non-high-risk AI systems** only very limited **transparency and information obligations** are provided (e.g., to flag the use of an AI system when interacting with humans). Nevertheless, the Commission encourages the providers of non-high-risk AI systems to apply **voluntarily** the mandatory requirements for high-risk AI systems by drawing up **ad-hoc codes of conduct**. In particular, according to the Commission, providers of non-high-risk AI systems may create and implement such codes of conduct themselves, which may also include voluntary commitments related, for instance, to environmental sustainability, accessibility for persons with disability, stakeholders’ participation in the design and development of AI systems, and diversity of development teams.

As highlighted by EIOPA, as of the date of this newsletter **no insurance-specific activities are included in the list of high-risk AI applications**. However, **IVASS** - as well as **EIOPA** - have already had the chance to underline the opportunity for insurance companies to **adapt voluntarily and progressively** to the ethical and protection principles that high-risk AI systems are inspired to, also by means of the implementation of the aforementioned codes of conduct. This taking into account the uptake of AI in the insurance sector.

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# The European Strategy on Digital Finance

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The expression “**Digital finance**” is used to describe the impact of new technologies on the financial services industry. It includes a variety of products, applications, processes and business models that have transformed the traditional way of providing financial services.

In this fast-moving environment, the European Commission embraced a process of “**digitalisation**”, i.e. the transformation of the European financial system and of the provision of financial services to Europe’s businesses and citizens.

Such process is carried out through a combination of various horizontal policies, mainly implemented under the umbrella of the Digital Single Market Strategy, the Data economy, as well as other sectoral initiatives such as the “**Digital Finance Package**” adopted by the Commission itself.

In such context, on 24 September 2020, the Commission presented its **Communication on a Digital Finance Strategy for the European Union** (COM(2020) 591 final). This strategy aims at ensuring a competitive, innovative and digitally-resilient financial market while at the same time preserving consumer protection and financial stability.

Indeed, an innovative, yet robust financial sector is vital to support the EU’s ambition for a recovery that embraces digitalisation and help to turn Europe into a global digital player.

The strategy sets out **four main priorities**:

- removing fragmentation in the Digital Single Market;
- adapting the EU regulatory framework to facilitate digital innovation;
- promoting a data-driven finance;
- addressing the challenges and risks with digital transformation, including enhancing the digital operational resilience of the financial system.

To this end, the Commission has identified as one of the priorities in its digital finance strategy the promotion of **data-driven finance**. The objective is to consolidate online access to the financial and sustainability-related data of companies and financial institutions in a single interface.

Besides, the “**open finance**” concerns the third-party service providers’ access to (business and consumer) customer data held by financial sector intermediaries and other data holders for the purposes of providing a wide range of financial and information services.

The open finance will contribute to the Commission’s cross-sectoral Data strategy for Europe, which envisages common European data spaces in several sectors of the economy and establishes cross-sector rules on data use.

In this context, **EIOPA’s draft response** to the EU Commission’s Digital Finance Strategy consultation dated 22 June 2020 shared the beforementioned four main priorities, including the **envisaged alignment of insurance regulation to the digital finance strategy outlined at European level**.

EIOPA underlined, in addition, how digitalisation offers significant opportunities to modernize the **insurance sector** and enhance more efficient supervision tools as well as new products and/or services, especially through the **use of data** and **AI systems**.

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# The European Strategy on Digital Finance: proposal for a Digital Operational Resilience Act

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**Digitalisation** and **operational resilience** in the financial sector are two sides of the same coin. Digital, or information and communication technology (ICT), gives rise to **opportunities** as well as **risks** which need to be properly understood and managed, especially in times of stress.

In this regard, on 24 September 2020, the European Commission came forward with the proposal for a regulation of the European Parliament and of the Council on "**Digital Operational Resilience for the Financial Sector**", so-called **DORA - COM (2020) 595 final**.

The proposal belongs to a larger digital finance package, which aims at developing a European approach that fosters technological development and ensures financial stability and consumer protection.

This package aims to ensure that the legal framework would not be an obstacle to the use of new digital financial instruments and that these new technologies and products are within the scope of financial regulation and operational risk assessment of companies operating in the EU. Thus, this proposal aims at supporting innovation and the uptake of new financial technologies while providing for an appropriate level of consumer and investor protection.

In the digital age, ICT supports complex systems used for day-by-day social activities. It keeps our economies running in key sectors, including **finance**, and enhances the functioning of the single market. However, increased digitalisation and interconnection also expand ICT risks making the whole society - and the financial system in particular - **more vulnerable** to cyber threats or ICT disruptions.

Indeed, while the universal use of ICT systems and high digitalisation and connectivity are core features of all activities of EU financial entities, **digital resilience** is not yet sufficiently built up in the operational frameworks.

Thus, the EU proposal, introducing a financial services digital resilience act, aims at strengthening the cybersecurity in financial services, addressing broader operation risks of banks, **insurance companies** and investment firms.

For these purposes, DORA sets uniform **homogeneous requirements** for the security of network and information systems of companies and organizations operating in the financial sector.

DORA, if approved, will cover a wide range of financial entities regulated at EU level, namely banking institutions, credit institutions, payment institutions, crypto-asset providers, **insurance and reinsurance undertakings**, etc.

Such financial entities will be subject to a set of different requirements and obligations according to their size, business profiles, as well as exposure to digital risk. They will be encouraged to share information in order to increase awareness of cyber threats and implement their defensive capabilities.

In light of the above, on 10 May 2022 the Council presidency and the European Parliament reached a **provisional agreement** on the Digital Operational Resilience Act.

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# The European Strategy on Digital Finance: Proposal for a Regulation on Markets in Crypto Assets

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**Crypto-assets** are digital representations of value or rights that have the potential to bring significant benefits to providers and consumers. In finance, crypto-assets are one of the major **distributed ledger technology applications** (DLT).

The European Union has stated and confirmed a policy interest in **developing** and **promoting** the uptake of transformative technologies in the financial sector, including blockchain and distributed ledger technology, while monitoring the relevant **risks** for **consumers**.

On 24 September, 2020, the European Commission came forward with the proposal for a regulation of the European Parliament and of the Council on **"Markets in Crypto-assets"**, so-called **MiCA - COM(2020) 593 final**.

This proposal is also part of the Digital Finance package, aimed at enabling and supporting the potential of digital finance in terms of innovation and competition while mitigating the related risks. Hence, it is in line with the Commission priorities to make Europe **fit for the digital age** and to build a **future-ready economy** that works for the people.

In particular, this proposal seeks to provide **legal certainty** for crypto-assets not covered by existing EU financial services legislation and establish **uniform rules** for crypto-asset service providers and issuers at EU level.

As reported by the Commission's President the scope of the proposal is to create *"a common approach with Member States on cryptocurrencies to ensure we understand how to make the most of the opportunities they create and address the new risks they may pose"*.

Furthermore, the Commission highlights that for crypto-asset markets to develop within the EU there is a need for a **sound, safe** and **proportionate legal framework**, clearly defining the regulatory treatment of all crypto-assets.

Such regulatory framework will protect **investors** and preserve **financial stability**, while allowing innovation and fostering the attractiveness of the crypto-asset sector. This will bring more clarity in the European Union, taking into account that some Member States already have national legislation for crypto-assets, but so far there is no specific regulatory framework at EU level.

In cooperation with national competent authorities, **EIOPA** regularly monitors the developments of crypto-assets markets and their impact on the **insurance sector** from a consumer protection and prudential perspective

In this regard, on March 17, 2022, **EIOPA, together with ESMA and EBA**, published a **warning for consumers on the risks of crypto-assets** where the three ESAs highlight, inter alia, that *"consumers should be aware of the lack of recourse or protection available to them, as crypto-assets and related products and services typically fall outside existing protection under current EU financial services rules"*.

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# The European Strategy on Digital Finance: Regulation on a pilot regime on infrastructures based on distributed ledger technology

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On 2 June 2022 was published the **Regulation (EU) no. 2022/858** of the European Parliament and of the Council of 30 May 2022 **on a pilot regime for market infrastructures based on distributed ledger technology (DLT)**.

The Regulation originates from the **proposal** submitted by the European Commission, together with the proposal on markets in crypto-assets, on 24 September 2020 (**COM(2020) 594 final**).

Such proposal was **part of a package of measures** to further enable and support **innovation** and **competition of digital financial services**, while mitigating the relevant risks. It is in line with the Commission priorities to reap all **the benefits of the digital age** and to **strengthen its industry and innovation capacity**, within **safe and ethical boundaries**.

The proposal for a regulation **on a pilot regime for market infrastructures based on distributed ledger technology**, and the proposal for a regime for crypto-assets, represented the **first concrete measures taken to**:

- **provide** appropriate levels of consumer and investor protection, for crypto-assets,
- **enable** innovative firms to make use of blockchain, distributed ledger technology ("DLT") and crypto-assets
- **ensure** financial stability.

The Regulation provides **legal certainty** and **flexibility** for market participants who wish to operate a **DLT market infrastructure** by establishing a **uniform set of requirements**. Permissions granted under the Regulation would allow market participants **to operate a DLT market infrastructure** and **to provide their services across all Member States**.

In particular, this Regulation defines a **"DLT market infrastructure"** either as **"a DLT multilateral trading facility (DLT MTF) or a DLT settlement system or a DLT trading and settlement system"**. Consequently, it establishes **operating and licensing conditions** for DLT market infrastructures, and the **supervision and cooperation** of competent authorities and ESMA.

In particular, the pilot regime for DLT market infrastructures shall allow such infrastructures to be **temporarily exempted** from some specific requirements under the Union financial services legislation that could otherwise prevent them from developing solutions for the trading and settlement of transactions in crypto-assets – which are one of the main applications of distributed ledger technology in the financial sector – qualifying as financial instruments.

The pilot regime shall also enable ESMA and the other competent authorities to gain experience on the **opportunities** and **specific risks** connected to crypto-assets that qualify as financial instruments, and their underlying technology.

According to the Regulation, however, the status of DLT market infrastructure should be **optional** and **should not prevent** financial market infrastructures **from developing trading and post-trading services and activities** for crypto-assets which qualify as financial instruments or are based on DLT, under the existing Union financial services legislation.

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# The European Strategy on Data: the Data Governance Act

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Over the last years, **digital technologies** have transformed the economy and society, affecting all sectors of activity and daily life. **Data is at the centre of this transformation**: data-driven innovation will bring enormous benefits for citizens, for instance through improved personalised medicine, new mobility, and its contribution to the achievement of the objectives of the European Green Deal, as well as in the insurance sector (including in motor and health insurance).

In its data strategy, the European Commission described the vision of a **common European data space**, a *single market for data* in which data could be used irrespective of their physical location of storage in the Union in compliance with applicable law. It also called for the **free and safe flow of data** with third countries, subject to exceptions and restrictions for public security, public order and other legitimate public policy objectives of the European Union, in line with international obligations.

Therefore, the European Commission proposes to establish **domain-specific common European data spaces**, as the concrete arrangements in which **data sharing** and **data pooling** can happen.

In order to turn that vision into reality, **on 25 November 2020**, the European Commission issued a **proposal** for a Regulation of the European Parliament and of the Council on **European data governance** (*Data Governance Act* - Brussels, 25.11.2020 COM(2020), 767 final).

The proposal led then to the approval, **on 30 May 2022**, of **Regulation (EU) 2022/868** of the European Parliament and of the Council on European data governance, amending Regulation (EU) 2018/1724 (*Data Governance Act*), which **entered into force on June 23, 2022** and will become **applicable starting from September 24, 2023**.

This new regulatory framework aims at fostering the **availability of data for use** by increasing trust in data intermediaries and by strengthening data-sharing mechanisms across the EU. As a result, together with the *General Data Protection Regulation* (GDPR) and *ePrivacy Directive*, the European Union intends to implement a **solid and trusted legal framework for the protection of personal data** and a standard for the world.

In particular, the new Regulation covers different types of data intermediaries, handling **both personal and non-personal data**, held by **public sector bodies** that is subject to rights of others. Thus, the same proposal **aims at facilitating data sharing**, reinforcing trust in data sharing intermediaries that are expected to be used in the different data spaces, and **not** at granting, amending or removing the substantial rights on access and use of data.

In order to create a fully horizontal framework, the Commission requires a **uniform application** of elements that does not leave margins of implementation to the Member States (including the **notification for data sharing service providers**, the mechanisms for **data altruism**, the basic principles that apply to the **re-use of public sector data** that cannot be available as open data and the set-up of **coordination structures** at European level).

In this new regulatory context, **IVASS** will be active in improving the activity of processing and use of data for the benefit of regulatory authorities, by implementing specific instruments aimed at allowing a more effective prudential supervision on undertakings' and market operators' behaviors (see IVASS strategic plan for the period 2021-2023).

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# The European Strategy on Digital Services: the Digital Services Act

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**Information society services**, including intermediary services, have become an important part of EU's economy, especially since the adoption of "*e-Commerce Directive*" (2000/31/EC), and contributed deeply to social and economic changes at European and International level

Digital services can support the achievement of **sustainable development goals** by contributing to economic, social and environmental sustainability. However, at the same time, the use of these services can also lead to **new risks** and **challenges** for the society and for the **individuals** using such services.

Aware of the importance of this topic, on **15 December 2020**, the European Commission issued a proposal for a Regulation of the European Parliament and of the Council on a **Single Market for Digital Services** and amending Directive 2000/31/EC (so-called **Digital Services Act** - Brussels, 15.12.2020 COM(2020) 825 final).

**"What is illegal offline should be illegal online"**: with this expression, the Commission's President has called for an **ambitious reform** of the existing EU e-commerce legal framework, which led to the political agreement reached on **23 April 2022** between the European Parliament and EU Member States on the proposal on the Digital Services Act (DSA).

Such proposal has been approved with amendments by the European Parliament on 5 July 2022, and then by the European Council on **4 October 2022**, together with the consistent **Digital Markets Act**. The new rules will be enforced first by the Commission for the largest online platforms.

The **scope** of the DSA is to **ensure** the best conditions for the provision of innovative digital services in the internal market, to **contribute** to online **safety** and the **protection** of fundamental rights, and to **set** a robust and durable **governance structure** for the effective supervision of providers of intermediary services.

In order to achieve these goals, the DSA sets out standard of **transparency, information obligations and accountability** for digital services providers. In addition, it advocates for a **public oversight** at EU and national level, and **cooperation** between competent authorities across jurisdictions in enforcing the law.

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# The European Strategy on Digital Services: towards a regulation concerning the protection of personal data in electronic communications

9 NOVEMBER, 4  
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On 10 January, 2017, the European Commission issued a proposal for a regulation concerning the **respect for private life** and the **protection of personal data** in **electronic communications** repealing ePrivacy Directive 2002/58/EC (Brussels, COM (2017) 10 final).

This proposal is a part of more comprehensive package on **digital finance**, which aims to develop a European approach that fosters technological development and ensures financial stability and **consumer protection**.

In accordance with such legal framework, this proposal aims at supporting **innovation** and the uptake of **new financial technologies** while providing for an appropriate level of **consumer** and **investor protection**.

In particular, the **Digital Single Market Strategy** pursues the objective to increase **trust** in, and the **security** of, **digital services**. To this end, the reform of the **data protection framework** - as envisaged by this proposal - represents a **key action**.

The proposal **does not** seek to introduce **a new regulation** on the protection of personal data in electronic communications but aims at reviewing the aforementioned ePrivacy Directive ensuring consistency with the General Data Protection Regulation.

Nowadays, indeed, **consumers** and **businesses** are increasingly relying on new internet-based services **enabling inter-personal communications** such as Voice over IP, instant messaging and web-based e-mail services, instead of traditional communications services (including in the **insurance** sector).

**Confidentiality** of electronic communications ensures that information **exchanged between the parties** are not to be revealed to anyone other than to the parties involved.

In light of the above, on **10 February 2021** a newly slightly amended proposal for the aforementioned regulation has been published. The member states, indeed, agreed on a **negotiating mandate** for revised rules on the **protection of privacy and confidentiality in the use of electronic communications services**.

Within this context, **EIOPA** - in particular, the **Consultative Expert Group on Digital Ethics in Insurance** - recognizes that there are many **opportunities** arising from **big data analytics** and **digitalisation** more broadly, but also some risks that need to be further addressed.

For this reason, EIOPA's Consultative Expert Group on Digital Ethics developed six AI governance principles to promote an ethical and trustworthy use of users' personal data in the European insurance industry. The principles developed by EIOPA's multidisciplinary stakeholder group take into account the specificities of the insurance industry and establish the key governance pillars for ethical and trustworthy digitalization in the insurance sector.

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# The European Strategy on Digital Markets: the Digital Markets Act

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On **November 1, 2022**, the “**Digital Markets Act**” (DMA) - originated from the **European Commission’s proposal** for a regulation of the European Parliament and of the Council on **contestable** and **fair markets in the digital sector** (Brussels, 15.12.2020 COM(2020), 842 final) - **entered into force**. This new Regulation (Regulation EU 2022/1925 of September 14, 2022) complements the **digital finance package**, in a view fully coherent with the Digital Services Act, thus implementing the Commission’s digital strategy in its contribution to ensuring a **fair** and **competitive digital economy**.

In particular, the new Regulation, whose effective implementation will occur in **May 2023**, intends to stop **unfair practices** by companies that act as “**gatekeepers**” in the online platform economy.

More specifically, the **objective** of the Regulation is to allow platforms to **unlock their full potential** by addressing at EU level the most relevant impacts of unfair practices in order to allow end users and business users **to exploit the full benefits of the platform economy and the digital economy at large**, in a competitive and fair environment.

For these purposes, the **Digital Markets Act** defines when a large online platform qualifies as a “gatekeeper”, establishing a list of “**do’s and don’ts**” that gatekeepers will need to implement in **their daily operations to ensure fair and open digital markets**.

These obligations will help to open up possibilities for companies to **contest markets** and **challenge gatekeepers** based on the merits of their products and services, giving them more space to **innovate**.

In this regard it shall be highlighted that, on the one hand, gatekeepers are defined as **digital platforms** that provide an important **gateway** between **business users** and **consumers** - whose position can grant them the **power** to act as a **private rule maker**, and thus creating a **bottleneck** in the **digital economy**.

On the other hand, **companies** operating one or more of **core platform services** (such as app stores, virtual assistants, cloud computing services *et similia*) **are qualified as a gatekeepers** if they meet specific **requirements**, i.e., (i) **a size that impacts the internal market**; (ii) **the control of an important gateway for business users towards final consumers**; and (iii) **an entrenched and durable position** (see Article 3).

In this perspective, the Digital Markets Act defines **a series of obligations** gatekeepers must respect to prevent and avoid the risk of **harmful effects of unfair practices** imposed by them from time to time.

Monitoring the **implementation** of such initiatives and acts is also a concern for the **insurance sector**, taking into account the impacts that **digitalization** and a **fair** and **contestable digital economy** may produce on supervision tools as well as new products and/or services.

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# The European Strategy on Cybersecurity: Directive on measures for a high common level of cybersecurity across the Union

11 DECEMBER, 14  
2022

On **November 10, 2022** the European parliament **approved** the **European Commission's proposal** for a directive of the European Parliament and of the Council **on measures for a high common level of cybersecurity across the Union** repealing Directive (EU) 2016/1148 (COM(2020), 823 final).

This new Directive will be part of a package of measures to **improve** further the **resilience** and **incident response capacities** of public and private entities, competent authorities and the Union as a whole, in the field of **cybersecurity** and **critical infrastructures protection**.

The Directive **is based on** – and **repeals** – Directive (EU) 2016/1148 on security of network and information systems (so-called “**NIS Directive**”) in order to take into account the increased **digitalisation** of the internal market in recent years and an evolving **cybersecurity threat landscape**.

The new Directive (also known as “**NIS2 Directive**”) aims at **removing divergences** in cybersecurity requirements and in implementation of cybersecurity measures in different Member States and intends to set the **baseline** for cybersecurity **risk management measures and reporting obligations** across all sectors that are covered in its Annexes I and II, and namely **essential sectors** and **important sectors** (such as energy, transport, banking, postal and courier services and digital infrastructure).

For these purposes, the NIS2 Directive sets out **minimum rules** for a regulatory framework and mechanisms for **effective cooperation** among relevant authorities in each Member State.

The NIS2 Directive **widens and strengthens the scope of application of the previous NIS1**, by enlarging both under a quantitative and qualitative perspective the perimeter of action and introducing a set of activities and constraints binding upon its recipients, especially as regards, inter alia, the security of the supply chain, cryptography of information, products certification for cybersecurity purposes etc. As result, in compliance with this Directive, Member States will be obliged to (a) adopt a **national cybersecurity strategy**, including **designating the competent national authorities**; (b) lay down **cybersecurity risk management and reporting obligations** for **essential entities** and **important entities**; and (c) lay down obligations on cybersecurity **information sharing**.

This new regulatory framework is consistent with the recent trends in the **insurance industry** (see, for instance, EIOPA guidelines on cybersecurity), which already foster the development of the approach to cybersecurity in terms of **proper self-assessment** and better **preparation of insurance companies to contrast cybersecurity risks**.

That being said, the current wording of the NIS2 Directive does not **expressly** include the **insurance sector** in its scope of application (other them, inter alia, the banking sector and the financial market infrastructures).

However, please note that the **final version** of the NIS2 Directive **could still be extended** also based on the final version of the **Directive on resilience of critical entities**, whose scope of application - which is not defined yet - is **expressly incorporated** by reference in the NIS2 Directive.

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# The European Strategy on Cybersecurity: Directive on the resilience of critical entities.

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The European Commission's proposal for a **directive on the resilience of critical entities (COM (2020) 829 final)** received the final approval by the European Parliament on November 22, 2022 and by the Council on December 9, 2022. The final text of the Directive should be published in the Official Journal of the European Union in the coming days.

This Directive sets out a Union framework for enhancing the resilience of **critical entities** considering their indispensable role - as **providers of essential services** - in the maintenance of vital societal functions or economic activities in the internal market in an increasingly interdependent Union economy.

In this perspective, the new Directive aims, first of all, at achieving a solid level of **harmonisation by identifying the sectors and categories of entities** falling within its scope; indeed, the internal market is characterised by **fragmentation** in this respect, with the consequence that today critical entities are not recognised consistently as such in all Member States.

In particular, the new Directive - in line with the recent "NIS2" Directive - covers **eleven "critical" sectors**, and namely **energy, transport, banking, financial market infrastructures, health, water, waste water, digital infrastructure, public administration, space and production, processing and distribution of food**.

The Directive sets forth a **procedure for the identification of critical entities** using **common criteria** based on an **assessment** of all relevant risks that may affect the provision of **essential services**, including accidents, natural disasters, public health emergencies such as pandemics, and antagonistic threats, including terrorist offences. In addition, the Commission is entitled to adopt a delegated act to **supplement the Directive by establishing a non-exhaustive list of essential services in the sectors and subsectors set out in a specific Annex to the Directive**.

Given the above, each Member State is then required to adopt a **strategy** for enhancing the resilience of the critical entities they identified, which shall set out **strategic objectives** and **policy measures** building upon relevant existing national and sectoral strategies, plans or similar documents, aiming to achieve and maintain a high level of resilience by critical entities.

Also, under the new Directive Member States shall **support critical entities** in enhancing their resilience through the development of guidance materials and methodologies, as well as by supporting the organisation of exercises to test their resilience, by providing advice and by training their personnel. Member States may also **provide financial resources** to critical entities, where necessary and justified by public interest objectives. Furthermore, Member States shall ensure that critical entities take **appropriate and proportionate technical, security and organizational measures** to ensure their resilience, based on the relevant information provided by Member States on each Member State's risk assessment and on the outcomes of the critical entity risk assessment. Also, Member States shall ensure that critical entities notify the competent authority, without undue delay, any incidents that significantly disrupt or have the potential to significantly disrupt the provision of essential services.

Even though the **insurance sector is not expressly included** in the scope of application of the new Directive, it cannot be excluded that the Commission will supplement the non-exhaustive list of identified sector by including insurance, considering the European legislator's attention on financial market infrastructures and operators.

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**ANIA**, the Italian Insurance Association,  
founded in 1944, is a voluntary non-profit association.  
Its main purpose is to develop and spread the culture of safety  
and prevention in our country, so as to protect both people  
and companies, and society as a whole, more and better.

Moreover, ANIA represents its members and the Italian insurance market  
vis-à-vis the main political and administrative institutions, including the  
Government and Parliament,  
trade unions and other social bodies.

The Association studies and cooperates in the resolution  
of technical, economic, financial, administrative, fiscal, social, juridical and  
legislative issues concerning the insurance industry.  
It supports and provides technical assistance to members,  
promotes the education and professional training of those  
working in the insurance sector.

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