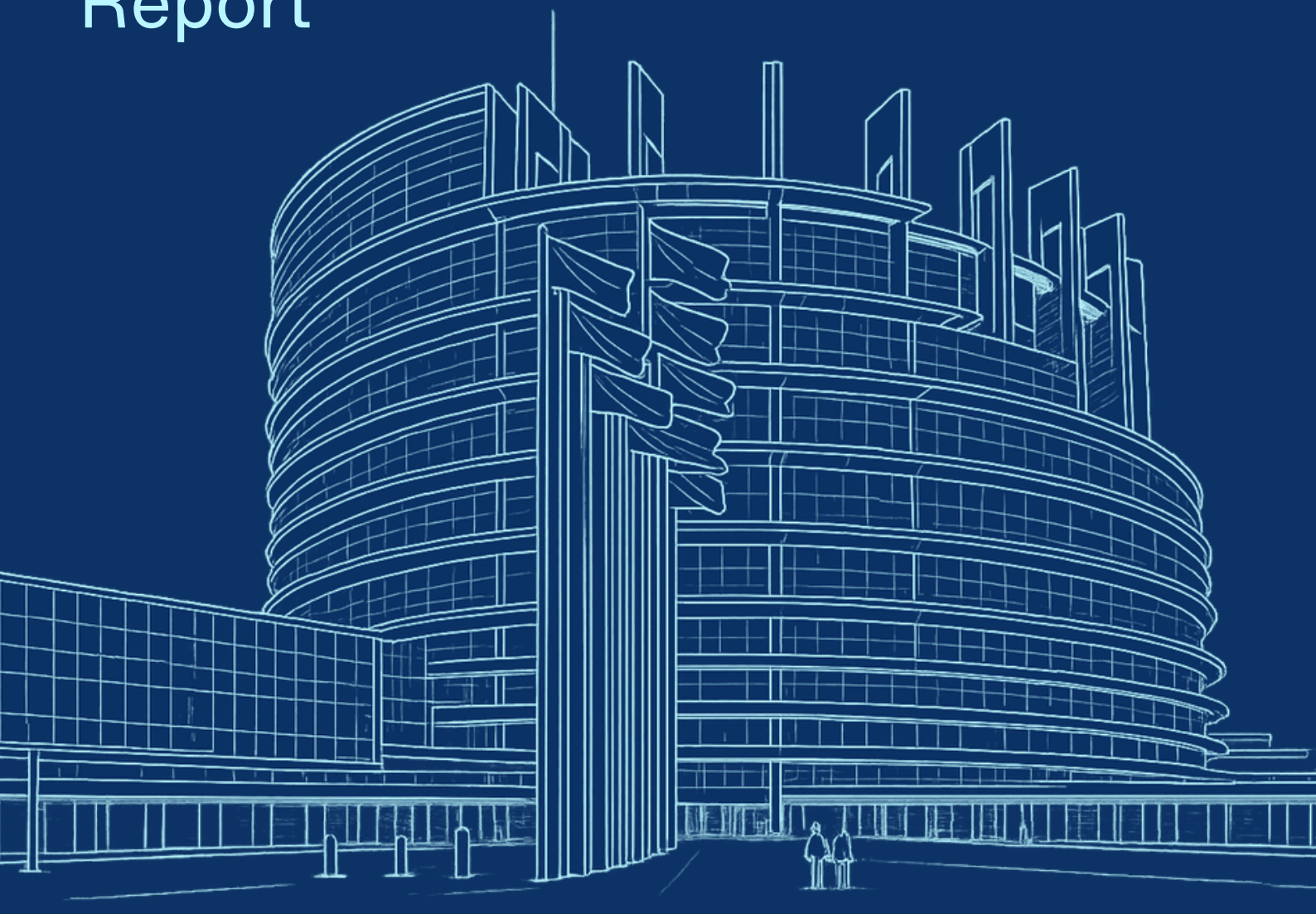
2025

BK AGENCY

REGULATORY HORIZON

Report



INTRODUCTION

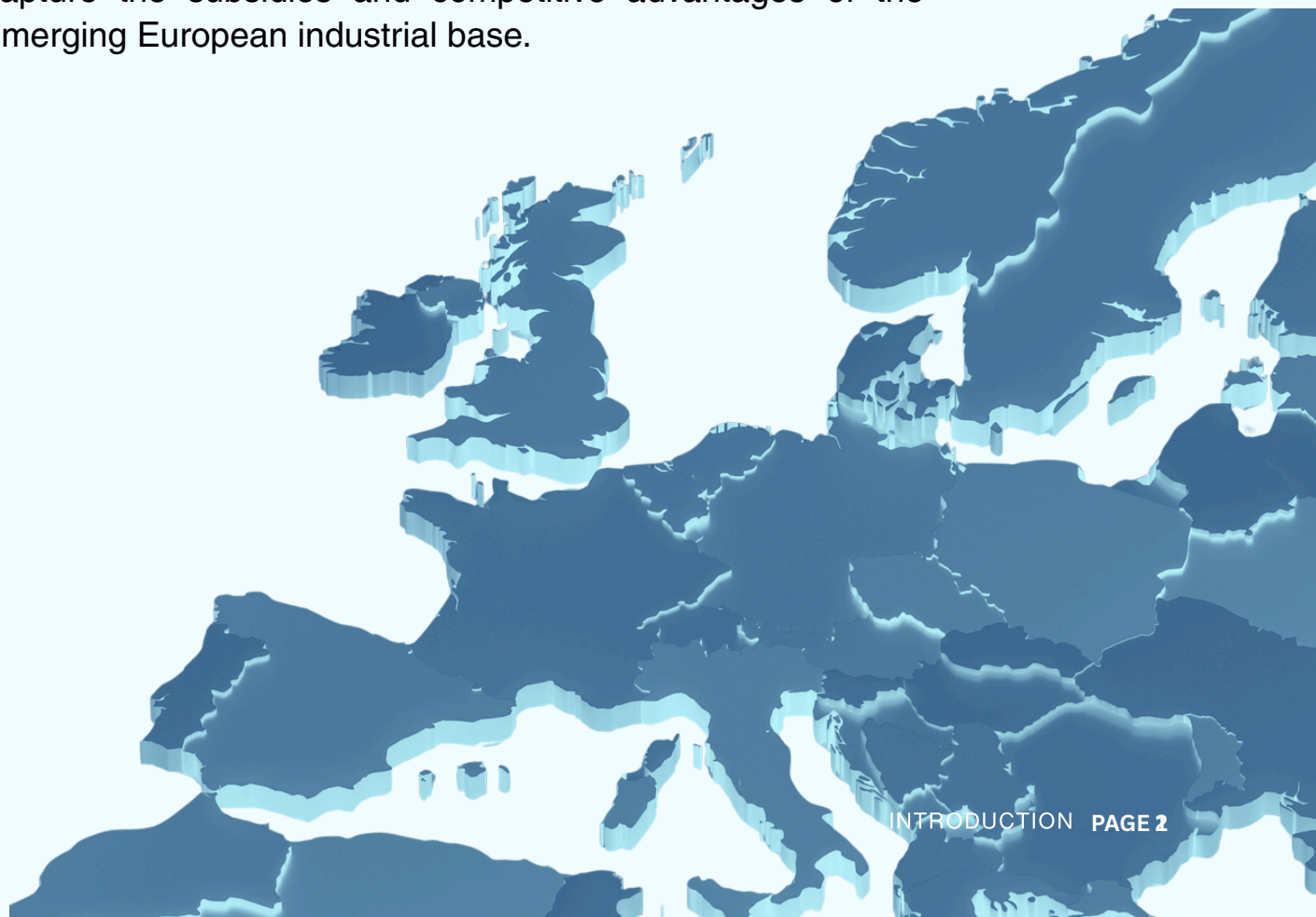
The year 2026 represents a shift in the European Union's regulatory philosophy, moving away from a traditional focus on consumer competition toward a model defined by strategic sovereignty.

This report analyses the legislative wave reshaping the internal market, where the European Commission is increasingly prioritising the development of a coordinated and self-reliant economy capable of enduring global geopolitical shifts. For businesses operating across the continent, this transition marks the end of the “untrusted” supply chain and the beginning of a period where regulatory alignment is a prerequisite for market access and public funding.

The following chapters detail a structural recalibration across several sectors. In telecommunications and defence, new frameworks such as the **Digital Networks Act** and the **European Defence Industry Programme** are designed to end market fragmentation by incentivising cross-border consolidation and regional self-reliance. Simultaneously, the energy and critical raw materials sectors are pivoting toward domestic processing and extraction targets to **reduce dependencies on non-EU actors.** Even within the consumer goods landscape, manufacturers face the changes of packaging and sourcing standards that elevate sustainability from a voluntary best practice to a legal requirement.

A primary takeaway of this regulatory cycle is the introduction of mechanisms intended to offset the cost of compliance. The proposed **28th Regime** offers a standardised corporate legal framework that could reduce the administrative burden of cross-border scaling by up to 40%. Furthermore, the **Defence Readiness Omnibus Act** and the **Industrial Accelerator Act** introduce unprecedented fast-track permitting processes, allowing critical projects in defence and energy to bypass traditional bureaucratic hurdles in as little as two months. These tools signal that while the EU is demanding higher security and environmental standards, it is also providing the legislative shortcuts necessary to achieve them.

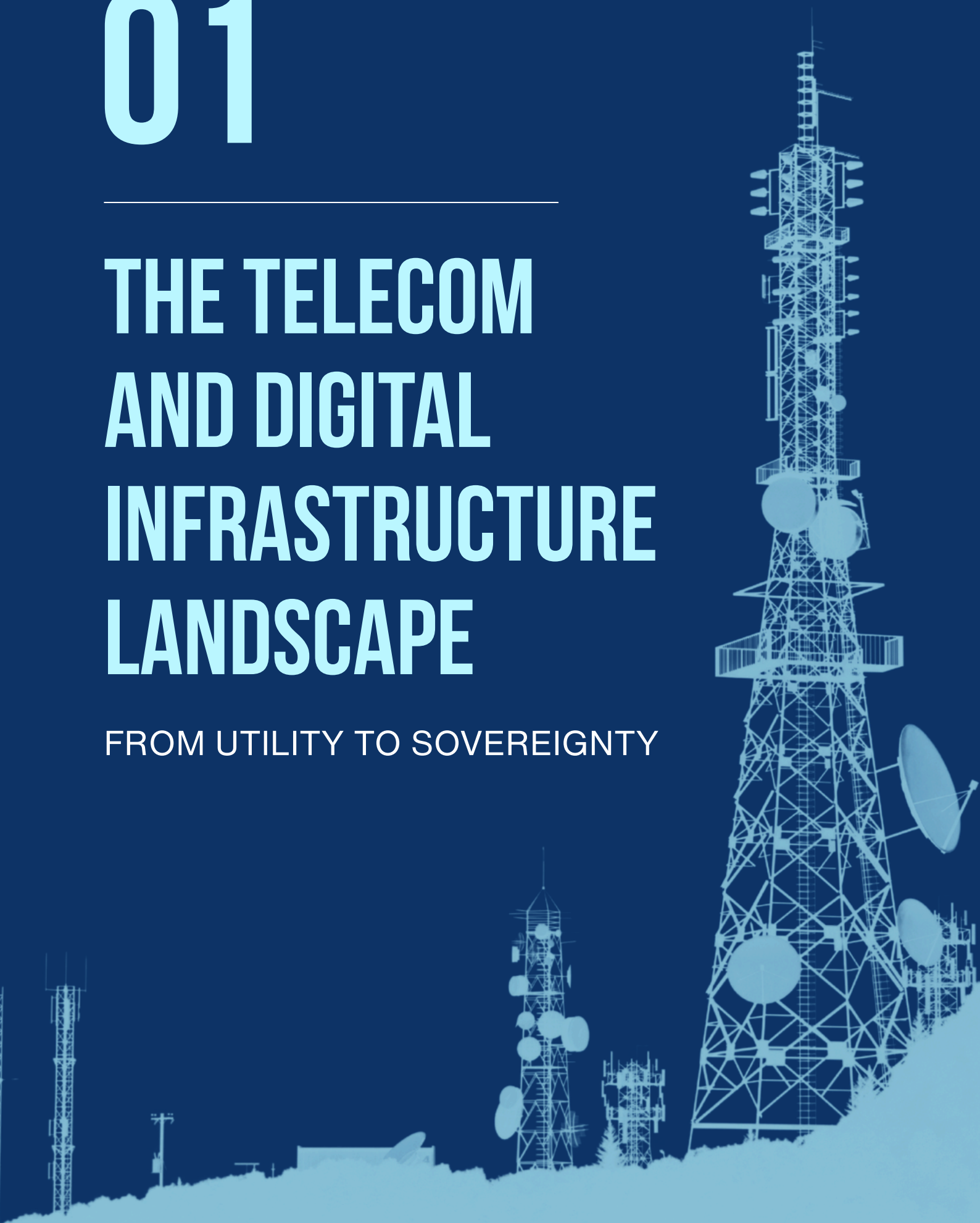
Ultimately, this report serves as a strategic roadmap for the year ahead. With the full application of directives like **NIS II** and the activation of **high-risk vendor bans**, corporate leadership is now directly accountable for supply chain integrity and cybersecurity resilience. Businesses that successfully integrate these new standards into their long-term planning will find themselves better positioned to capture the subsidies and competitive advantages of the emerging European industrial base.



01

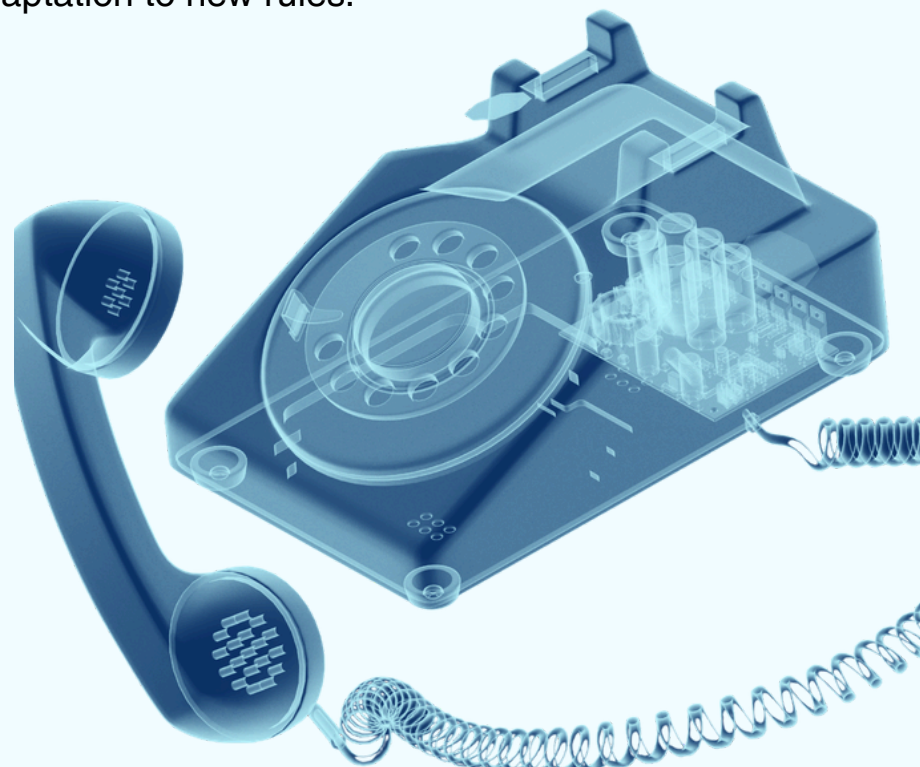
THE TELECOM AND DIGITAL INFRASTRUCTURE LANDSCAPE

FROM UTILITY TO SOVEREIGNTY



For several decades now, the European Union's approach to telecommunications has been defined by a single word: competition. The EU's priorities were breaking up national monopolies, lowering prices for the consumers, and ensuring that everyone can get an affordable DSL connection. One could argue that such a strategy worked. European consumers enjoy some of the lowest mobile and broadband prices in the western world. The new goal that Brussels is trying to achieve is **strategic sovereignty.** Inspired by the trend-setting 2024 Mario Draghi's and Enrico Letta's reports, the European Commission has acknowledged that even though prices are low, the underlying infrastructure is fragmented and unable to keep up with the newest technological advancements. Europe currently consists of 27 mini-markets while the United States and China treat their networks as singular engines for industrial growth.

There are two pillars of this new era that need to be examined: the Digital Networks Act and the Cybersecurity Act II, alongside the immediate enforcement of the Gigabit Infrastructure Act and security directives. For businesses in the telecom field, it is safe to claim that the 2026 will be the year of the consolidation and adaptation to new rules.



DIGITAL NETWORKS ACT

The Single Market Reset

Unveiled in January 2026, the DNA is a declaration that the EU wants to move away from 27 national versions of telecom regulation toward a unified digital continent. The most immediate win for cross-border operators is **the Single EU Network Passport system**. Currently, if an operator wants to expand from Estonia into Portugal, they face the administrative hurdle of separate notifications and local paperwork that needs to be filed. The DNA replaces this with a model managed by the newly formed Office for Digital Network, through which they would be allowed to **notify once and operate everywhere** in the union. This lowers the barrier to entry for medium-sized players and allows pan-European companies to centralise their compliance teams in one capital.

A significant challenge for telecom corporations has been the so-called **spectrum lottery**. Licenses in one country might last 20 years, while the other Member State grants them for 80 years, creating a massive unpredictability for investment. The DNA now pushes for lifelong or significantly extended licensing. Instead, the Commission is introducing a "use it or share it" rule: If an operator sits on spectrum without using it, they will be forced to share it with competitors or satellite providers. This is a clear signal that the EU will provide stability, but the industry must provide coverage in the market.

Transition from Copper to Fiber Networks

For over a hundred years communication relied on copper networks: The first versions of the Internet were rolled out on copper cables. Today, people expect faster connection, and copper can no longer keep up. Over the past fifteen years, fiberhave grown fivefold, outperforming copper in speed, distance, and bandwidth, creating a foundation for future technologies such as 6G and AI.

The EU has set a hard deadline for the retirement of copper networks: December 31, 2035. The roadmap begins now, and the companies in the industry could already start preparing for the switch-off. By June 2029, Member States will have tocomplete milestones in their transition to fiber optic networks. For legacy operators, this will be an expensive rule that will force them to switch to fiber or risk becoming significantly less competitive. For fiber-only players, it's nothing but good news.

Businesses should expect localised disruptions in areas where copper is retired, requiring a proactive migration of IoT and legacy systems to fiber or 5G. Lastly, DNA introduces the voluntary conciliation facility. The Commission will now facilitatenegotiations between "large traffic generators" (in other words, large tech companies) and telecom firms to reach commercial agreements on traffic costs. Even though the term itself suggests that meetings would be voluntary, mandatory measures might be introduced in 2027.

THE CYBERSECURITY ACT

Building the Fortress

If the DNA is about building the new infrastructure for service providers, the CSA II, which was proposed in January 2026 and is highly likely to pass during the first half of 2027, creates a high-risk vendor framework to ensure that the critical components powering these networks are sourced from trusted and secure suppliers. Cybersecurity is the backbone of European security and therefore is an integral part of EU's "security by design" strategy built to address growing challenges from infrastructural fragmentation and threats from hostile actors.

To address these issues, the Act aims to create a unified rulebook for all Member States and build conditions for a better due diligence of the supply chain.

"CYBERSECURITY IS THE BACKBONE OF EUROPEAN SECURITY AND THEREFORE IS AN INTEGRAL PART OF EU'S "SECURITY BY DESIGN" STRATEGY BUILT TO ADDRESS GROWING CHALLENGES FROM INFRASTRUCTURAL FRAGMENTATION AND THREATS FROM HOSTILE ACTORS.

High-Risk Vendors and Maximum Harmonisation

This year marks the beginning of a 3-to-5-year phase-out window for high-risk hardware, which represents an increased business risk for companies that rely on such hardware. Industry players, particularly those coming from the countries that heavily rely on Chinese equipment such as Cyprus or Austria, would have several years to prepare, giving them time to physically replace all hardware. Should the new rules have come into effect immediately, an internet crash would have been guaranteed. For instance, for established companies that built their networks early and are heavily reliant on Chinese equipment, the cost of phasing out Chinese tech and replacing it with something else will likely be measured in billions. For smaller brands that often used Nokia's or Ericsson's hardware from the start, the negative impact will be lower. Investors are already pricing this fact into the valuations of major European telecommunication companies, lowering their estimated value.

Additionally, the Commission aims to ensure that cybersecurity rules are aligned for all Member States. Compliance will no longer be a local discussion, but something to be determined in Brussels. Instead of engaging with regulators across all 27 states, companies will now need to reach consensus on the EU level. However, should Brussels decide against a supplier, the company will effectively be locked out of the continent for good, while with the current rules if a negative decision was made on a local level, such as in Budapest or Dublin, the company would only lose one national market and still potentially have access to other states.

Importantly, the EU Agency for Cybersecurity (ENISA) is being transformed from an advisory body into a centralised watchtower. Under the new act, ENISA will have the power to conduct a process called Strategic Supply Chain Reviews. Instead of just examining the code, they will look at the corporate headquarters. If a vendor is deemed a subject to the influence of a non-democratic third country, ENISA can recommend a block.

THE IMMEDIATE HORIZON

As both DNA and CSA II have been unveiled in late January, the next several months will be crucial for polishing the text of the regulations and determining their scope and influence.

First, the Digital Networks Act is intended to replace the Electronic Communications Code, adopted as a directive. Unlike the directives which allow for the more flexible implementation within individual Member States, regulations impose strictly the same rules across the Union. Some Member States already push back, arguing they need a directive with more flexible rules to maintain national control. If the “single passport” makes it through the Parliament's amendments, it will represent a big change for cross-border mergers and acquisitions in the coming years.

However, legacy operators are expected to fight the copper switch-off mandates set for 2035 to protect their existing margins. They view the old copper networks as almost pure profit – these networks are already built in the ground and functioning, so the customers who stay on copper networks are cheaper for the firm. Transitioning to fiber would necessitate a huge investment, often measured in billions of euros.

Unlike the original Cybersecurity Act from 2019 which centered on whether the systems were secure, the focus of the new CSA is on who builds those systems and creates a trusted ICT supply chain framework – a network of suppliers, manufacturers, and service providers of tech products. This framework will allow the Commission to bypass national governments to ban high-risk vendors across the EU.

The Gigabit Infrastructure Act: The Field Wave

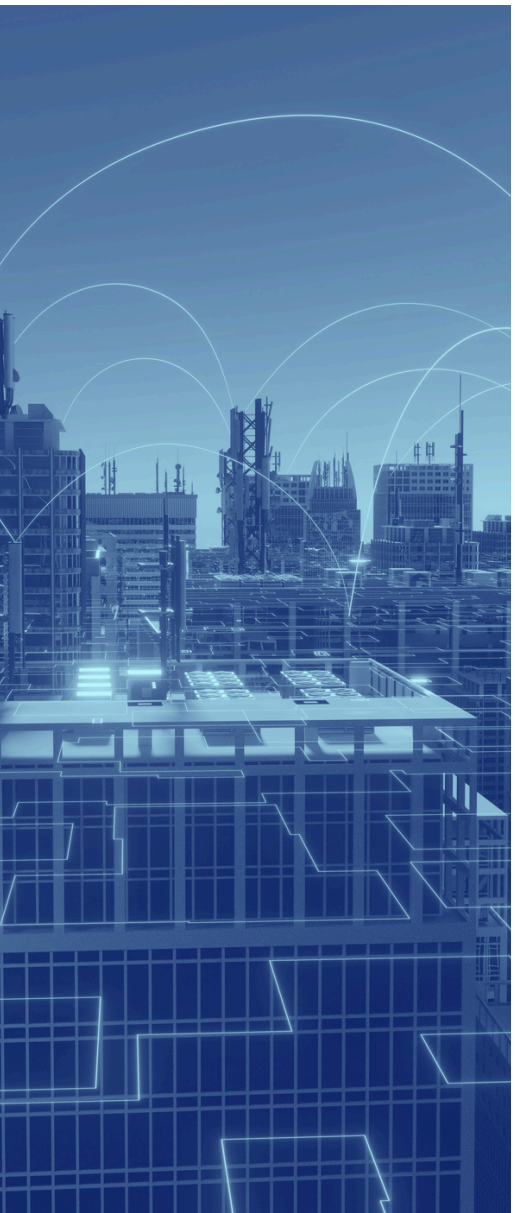
The GIA, which became applicable in late 2025, is a set of EU-wide rules that make it faster and less expensive to build digital networks. For example, if the water supplier is escavating a street to repair a pipe, it needs to coordinate with telecommunication providers so that the fiber can be laid in the same spot. Even though the Gigabit Infrastructure Act has already entered into force, its heavyweight provisions will come into effect only in May 2026.

One of the most significant rules is that if a local authority doesn't respond to a permit application for 5G towers or fiber digging within four months, the permit is deemed as granted**.** Additionally, as of February 2026, all new or majorly renovated buildings must be pre-equipped with fiber-ready infrastructure. This implies that the architects and real estate investors will need to incorporate fiber infrastructure in the project designs. Consequently, the buildings that do not have optical networks will likely see a drop in market value.

Full Application of the NIS II Directive

2026 will be the year when the new Network and Information Systems Directive stops being a planning exercise and starts being a strict audit reality: the deadline to turn the Directive into the national laws has passed.

NIS II is made to protect critical infrastructure such as energy grids from cyberattacks or shutdowns. Most importantly, management bodies, such as supervisory boards and boards of directors, can now be held personally liable for cybersecurity failures, and organisations will need to report significant incidents within 24 hours. This applies to both the developers of cybersecurity tech and the end-users. In 2026, the first test cases of these fines are expected. They can reach up to 10 millioneuros or 2% of global turnover and will be issued by designated national authorities. The company might face different levels of severity across countries, but the Directive still sets the minimum fine amount, so that the rules are relatively harmonised.



Transitioning Towards the Edge Cloud

On 3 March 2026, the Commission announced the European Cloud-Cloud Continuum (EURO-3C) project worth 75 million euros. This is the first large-scale attempt to build a federated telco-edge-cloud. Instead of relying on a single data center outside European borders, edge cloud means deploying small but powerful servers directly within telecom towers on European soil. Since the goal is to create a federated cloud, all participating companies will have to connect their local edge servers into one large network. This signals EU's plan to move processing power away from giant American data centers and embed it directly within the telecom network. For businesses, this means lower latency for industrial automation and a more sovereign way to store data.

WHAT SHOULD THE BUSINESS EXPECT

The regulatory landscape of 2026 is moving toward predictability, but at a price. To stay ahead, business in the telecom and digital sectors should be prepared for the new legislative developments.

1

First, audit the supply chain. Rather than wait for the "high-risk" list from ENISA, it is advisable to identify dependencies on non-EU vendors soon.

2

Secondly, the Gigabyte Infrastructure Act's tacit approval for network expansion can be used to benefit the business. If the company is waiting too long for the permit to be issued, they can now use the new 4 months rule to move forward.

3

Lastly, it is recommended to prepare for the NIS II audits which will be performed by national authorities to make sure that the leadership of a company is personally overseeing cyber-risk management. Business should ensure that the boardroom-level reporting structures are in place and function well. The grace period for learning the rules is officially over.

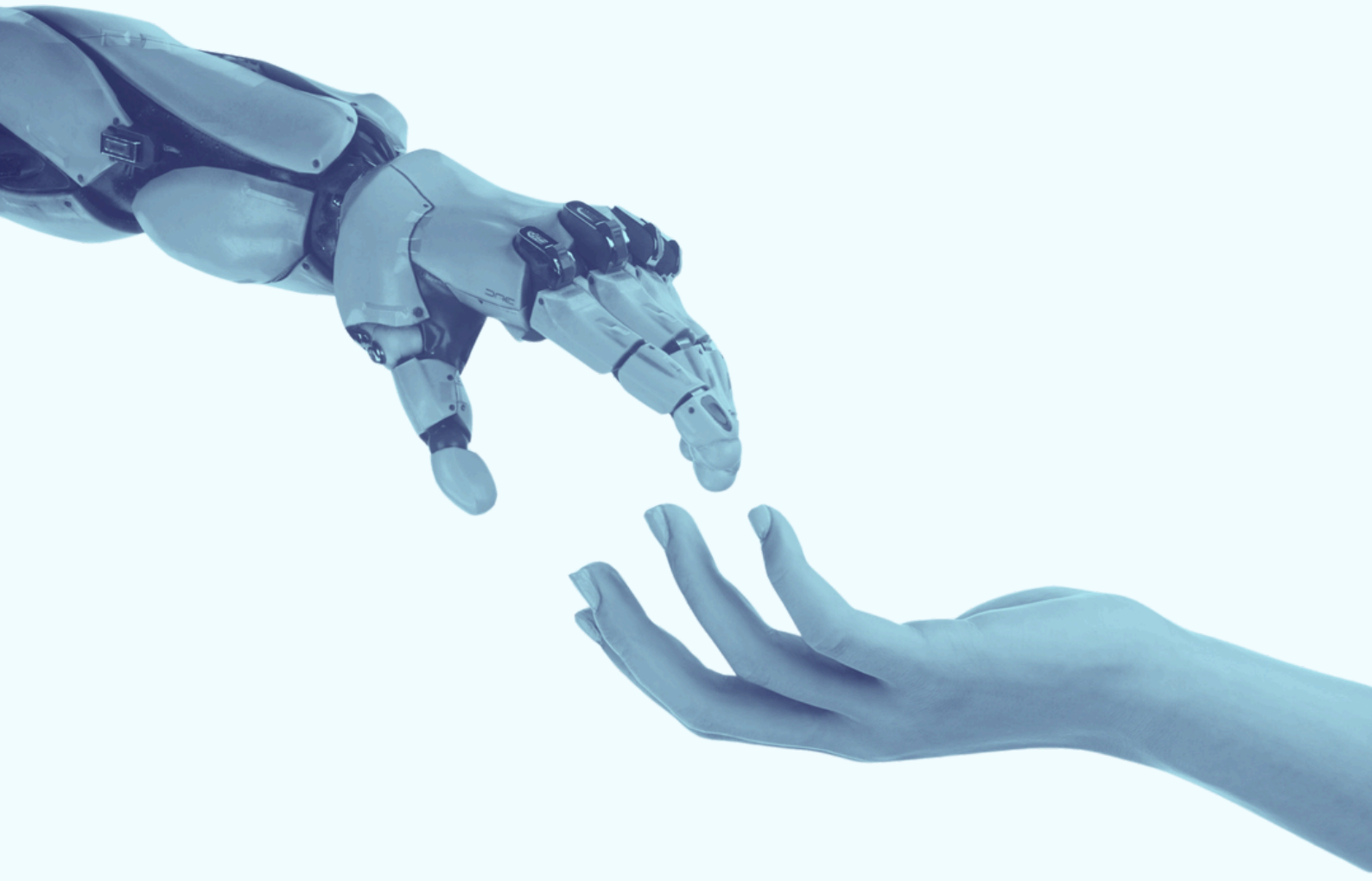
The European telecom sector is being rebuilt as the backbone of the the Union's security. Those who adapt to the sovereignty model will find opportunities for scaling up, while those who stay attached to the national utility model may find themselves left behind by the DNA's fast-moving timelines.

02

THE DIGITAL AND AI OMNIBUS

UPDATES TO THE CYBER REGULATION

In late 2025 and in the first quarter of 2026, the European Commission introduced a dual-track legislative package known as the Digital Omnibus. This package consists of the Digital Omnibus Act and the AI Omnibus, and it is not simply a set of new regulations, but rather an instrument that is designed to internal contradictions and lower the administrative burden on businesses. This shift is expected to help EU reach its goal of reducing reporting obligations by 25% to boost industrial competitiveness.



THE DIGITAL OMNIBUS:

Key Provisions Regarding Data and Cyber Landscape

One of the primary legal challenges in the cyber world today is the so-called compliance fragmentation. One data breach or cyberattack could trigger different reporting requirements under four different laws (GDPR, Network and Information Systems Directive, Digital Operation Resilience Act, and the Data Act). Those requirements sometimes had conflicting timelines and formats, and the Digital Omnibus aims to address this through several structural changes. The Act establishes a Single Reporting Portal for all cybersecurity and data incidents. Instead of notifying multiple national and EU authorities, a business can send a single digital notification. The portal then automatically routes all the relevant data to the necessary regulators, thus ensuring efficiency of reporting just once.

Contrary to what was the standard in the early GDPR era, the Omnibus moves away from intrusive cookie banners. It introduces browser-level preference signals, allowing users to set their privacy choices once at the software level. Websites are legally required to respect these signals automatically, eliminating the need for accept/reject pop-ups all the time and lowering the technical expenses for businesses that are web-based.

Finally, to encourage AI development, the Omnibus clarifies the definition of pseudonymised data. It establishes that if the holder of the data can't reasonably re-identify individuals, that data may be treated as non-personal in specific research and industrial contexts. This creates a safe space for training models without the whole administrative weight of the GDPR's personal data requirements.

UPDATING THE RULES ON ARTIFICIAL INTELLIGENCE:

AI Omnibus

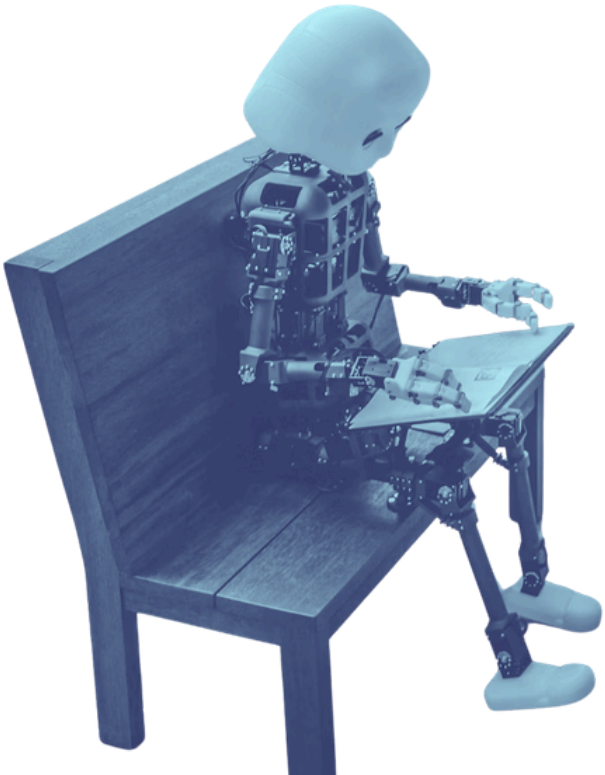
While the AI Act that entered into force in 2024 set the standard for safety, its implementation was met with an industrial reality check. The AI Omnibus, agreed upon by the Parliament in March 2026, serves as an adjustment that would ensure the Act does not become a constraint on innovation for European tech firms. The most visible change is the postponement of the high-risk AI deadlines. Under the original rules, obligations for high-risk systems were set to apply in August 2026. However, due to delays in the development of harmonised standards (the technical blueprints companies must follow to prove compliance), the Omnibus has extended these deadlines. Obligations for systems in areas such as biometrics or critical infrastructure are now expected to apply in December 2027, while AI embedded in regulated products (e.g. medical devices or vehicles) has been pushed to August 2028. This pause gives the industry the time it needs to adapt to the technical standards once they are made final.

A key challenge in AI development is that removing bias from a model requires developers to access the very sensitive data (those include race, health, etc.) that must be protected. The AI Omnibus creates a **specific GDPR exemption for de-biasing**. It allows companies to process special categories of personal data for the strict purpose of identifying and correcting discriminatory patterns in high-risk AI systems, under the condition that the tight security safeguards are in place. The Omnibus also addresses the rise of generative AI by introducing a specific grace period for content watermarking. Providers of AI systems already on the market before August 2026 now have most likely until November 2026 (the exact timeline will depend on the final trilogue agreement) to implement technical markers that identify synthetic audio, images, or text. This approach allows existing products to remain on the market without interruption and at the same time provides companies the necessary time to integrate mandatory safety features like AI content watermarking.

STRATEGIC IMPACT

The Digital and AI Omnibus packages intend to aid companies by securing a more predictable market by harmonising conflicting rules and reducing legal uncertainty. By simplifying the registration of low-risk systems, the EU is attempting to lower the entry barrier for SMEs and small mid-caps. This transition represents a shift from a top-down regulatory approach which was focused primarily on prohibitions and penalties toward a model that prioritises simplifying business operations for compliant companies. At the same time, it aims to maintain strict security and sovereignty standards. In this new framework, the European Union is expected to act less as a distant enforcer and more as a strategic partner that removes administrative burden for those who align with the Union's security and industrial goals.

Companies that proactively align their supply chains and data management with these standards will gain a competitive edge – they will be shielded by EU regulations that restrict market access for high-risk foreign rivals, while simultaneously benefiting from the expedited administrative processes that allow for faster expansion across the entire European market.



> ***THE DIGITAL AND AI OMNIBUS PACKAGES INTEND TO AID COMPANIES BY SECURING A MORE PREDICTABLE MARKET BY HARMONISING CONFLICTING RULES AND REDUCING LEGAL UNCERTAINTY.***

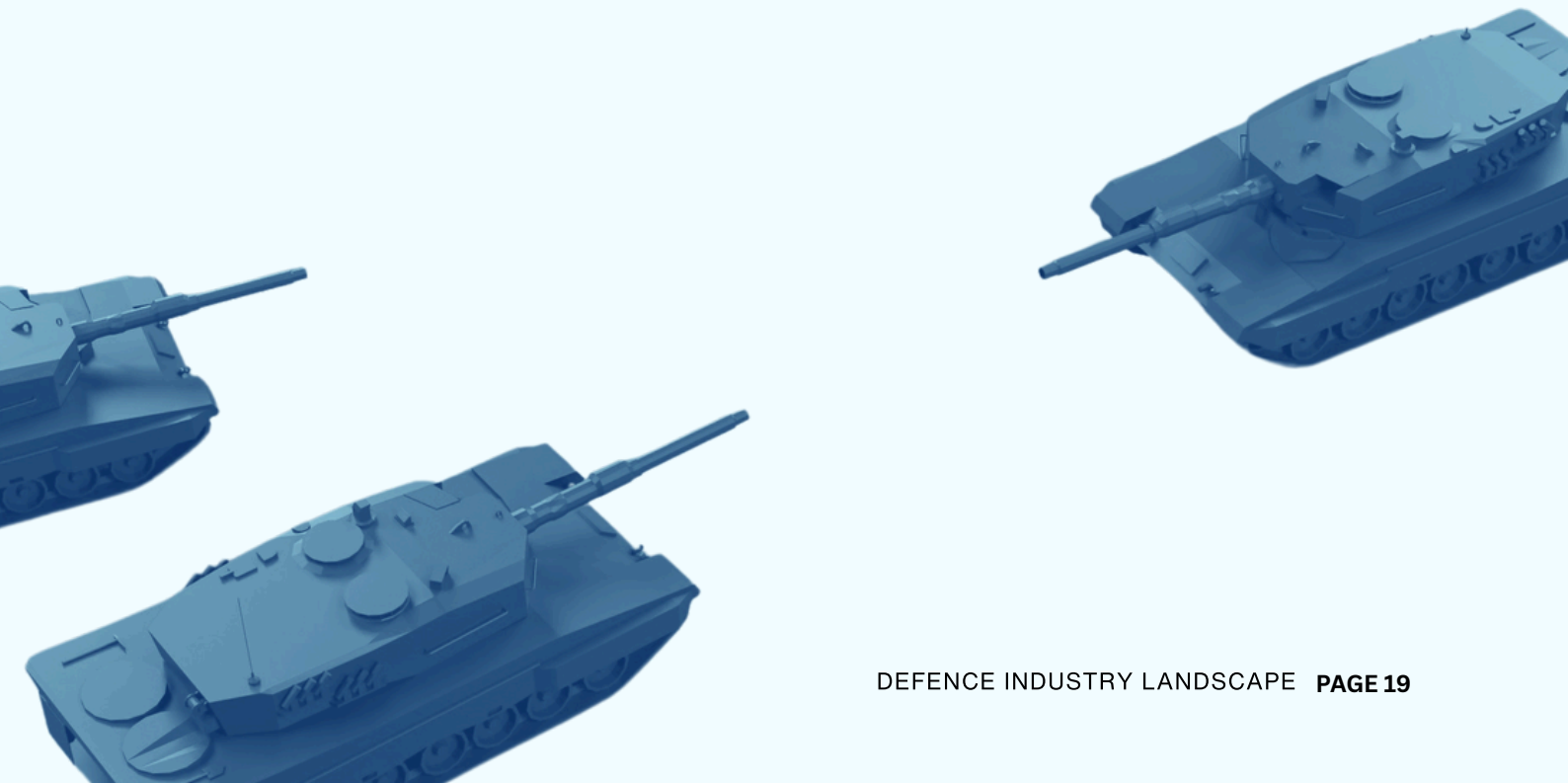
03

DEFENCE INDUSTRY LANDSCAPE

A NEW BEGINNING

Until 2025, the European defence sector operated as a collection of 27 separate national boutiques that produced high-end equipment in small batches for domestic use. The production has been highly specialised, relatively costly, and smaller in quantity. That era ended with “Europe’s independence moment”, as presented in the Commission’s 2026 Work Programme.

Today, the European Union is officially on track to transition into a coordinated defence economy. The goal has now evolved from buying together to building together, at a scale that can satisfy the needs of the continent in a major peer-to-peer conflict. The Russian invasion of Ukraine, now in its fifth year, and shifting US priorities have forced a larger focus on sovereignty in Brussels. Thus, the European Union now aspires to become an active industrial leader in defence. For the stakeholders involved in the industry, this represents one of, if not, the most significant shift in market dynamics since the end of the Cold War: an accelerated transition from national procurement to a world of industrialisation on a wider European scale.



THE KUBILIUS WHITE BOOK

500 Billion Euro Investment Project

The White Paper for European Defence Readiness 2030 (commonly referred to as the Kubilius Book after its author European Commissioner for Defence and Space), presented last year, remains the foundational text for current defence policy. With the key message if you want to avoid war, you must prepare for war, the White Book highlights an urgent necessity for all Member States to build defence capabilities together. For industry players, the EU has identified an investment gap of 500 billion euros to achieve credible deterrence by 2030.

One of the most critical regulatory shifts in 2026 is the activation of the National Escape Clause regarding defence spending. The EU's strict debt and deficit rules (such as the 3% limit) traditionally forced governments to choose between social spending and defence. In the new reality where the goal is strategic autonomy, defence spending is now exempt from the fiscal calculations if it is directed toward EU-coordinated projects. This has unlocked a big wave of national orders that were previously at a standstill. Defence contractors are experiencing a multi-year order book, which allows for more long-term planning and capital investment that was nearly impossible in the era of year-to-year budgeting.

Flagship Capabilities

Kubilius' report identifies four flagship areas where the EU centralises its funding:

- **Integrated air and missile defence,** bringing the bloc closer to the unified European Air Shield;
- **The EU cyber shield** to protect critical digital infrastructure;
- **The eastern flank infrastructure –** introducing the high-tech "smart borders" from the Baltic to the Black Sea;
- **Military mobility 2.0** to harden the continent's transport logic for rapid deployment.

THE EUROPEAN DEFENCE INDUSTRY PROGRAMME

New Rules

As the White Paper is not legally binding, EDIP is one hard-law example. The Programme became fully operational in February 2026, and focuses on the mechanism that changes the way of bidding for contracts. It is specifically designed to reducemarket fragmentation by making it financially irrational to purchase non-European or non-coordinated equipment.

The EDIP introduces the Structure for European Armament Programme. This is a new legal entity that allows Member States to cooperate on a specific project (for example, a new armored vehicle or a tactical radio system). If a project is run via a SEAP involving at least three Member States, it is fully VAT exempt and is eligible for a 25% direct EU cash funding for production costs. Defence companies should recognise that this means bidding alone is not as preferrable as it used to be. To access the highest profit margins and EU subsidies, a company must form a cross-border industrial partnership. A project involving a prime contractor from one country, an engine manufacturer from the other, and a sensor specialist from the third is now significantly more profitable than a completely national bid.

The EDIP has set a quite enthusiastic target. By 2030, at least 50% of the defence budget of Member States must be spent on products manufactured within the European Defence Technological and Industrial Base. This is a sign that the EU is starting to incentivise regional self-reliance compared to global procurement. While American and Israeli tech remain vital for Europe's immediate readiness and the global defence supply chain, the financial incentives are now tilted heavily toward firms that manufacture and hold intellectual property within the EU.

THE DRONE REPORT

The Shift from High Quality to High Quantity

In early 2026, the European Parliament adopted the “Drones Report” presented by Latvian MEP Reinis Pozņaks, which brins the experience of world-class frontline drone operators, research and real-time war experience from Ukraine, Israel, and their partners. It mainly argues that Europe’s current drones are too expensive to lose and at the same time too slow to produce. The report mandates a regulatory change that would be directed towards standardised interfaces – the Commission is now drafting technical standards for drone components (like batteries or flight controllers). Future EU-funded contracts will require that hardware is interoperable by design.

The EU will likely move from buying several very high-quality drones to buying higher volume of drones that are tactical-grade and easier to produce. Additionally, the report included a strict ban on high-risk components from jurisdictions that are deemed non-democratic. For manufacturers, this means an immediate supply chain audit is required to purge components that could lead to an ENISA-led ban under the Cybersecurity Act.

OMNIBUS AND ESG

Arguably one of the biggest issues for the defence industry has traditionally been bureaucratic red tape and the banks’ reluctance to lend to certain arms companies. Both issues are likely to be addressed in the immediate future by theCommission's Defence Omnibus act, a package that attempts to lower the regulatory burden on the bussiness. The Act has introduced a 60-day fast-track permit for every industrial project deemed critical for defence readiness. If a corporation is building a new munitions factory or a secure R&D center, the usual environmental and local zoning inconveniences can be bypassed in two months. This is a pretty significant departure from traditional EU administrative law.

Alongside bureaucratic relief, the Commission and the European Investment Bank have now clarified that the defence can be compatible with ESG goals. The EIB has opened a 3 billion euros lending facility specifically for dual-use and resilience infrastructure. This has effectively lowered the cost of capital for defence firms in Europe.

THE IMMEDIATE HORIZON

Next Months

In the next three months, the first joint procurement call under European Defence Industry Programme is expected to happen. Specific technical requirements for the products will be of interest, as those will set the standards for the foreseeablefuture of European military equipment.

By the end of the year, the Commission is expected to publish the high-risk vendor list for defence supply chains. This list will explicitly name companies whose components are banned from any defence projects funded by EU.

Defence companies can also expect the rollout of European Defence Equity Facility in the next 12 months. EDEF will resemble a venture capital fund designed to prevent promising EU defence start-ups from being bought out by the investors from China or the US.

To increase the likelihood of succeeding in this new regulatory environment, businesses should be mindful of several key changes.

First, defence companies could embrace dual-use designs. One of the simplest paths to funding is to demonstrate that a company's technology has both civilian (e.g. in energy or logistics) and military application. Resilience funds are larger than the funds limited to defence only. Simultaneously, the EU aims to increase industrial interoperability by having fewer types of tanks and radios. Companies that lead the way in standardisation and align with the modularity rules will become the platform that others will have to build upon. Finally, securing a clean supply chain is of utmost importance, as even a single high-risk component in the product can disqualify a multi-billion euros SEAP bid. **Sovereignty of the supply chain is now both a security necessity and a competitive advantage.**

The next months will be an essential window for strategic positioning. Companies should start to identify potential partners in at least two other Member States to partner up early and be ready for the SEAP calls. Naturally, auditing the shadow supply chain and making sure that the suppliers are trusted vendors by the EU standards will be crucial. Defence contractors should also leverage the new Omnibus rules – if there is an expansion that has been delayed due to the local red tape, thisis the time to apply under the new 60-day rules. In this new era for the defence industry, competition is set to grow, and the champions of the sector will be those who adapt fastest to the new rules and start thinking beyond national borders and local industry.

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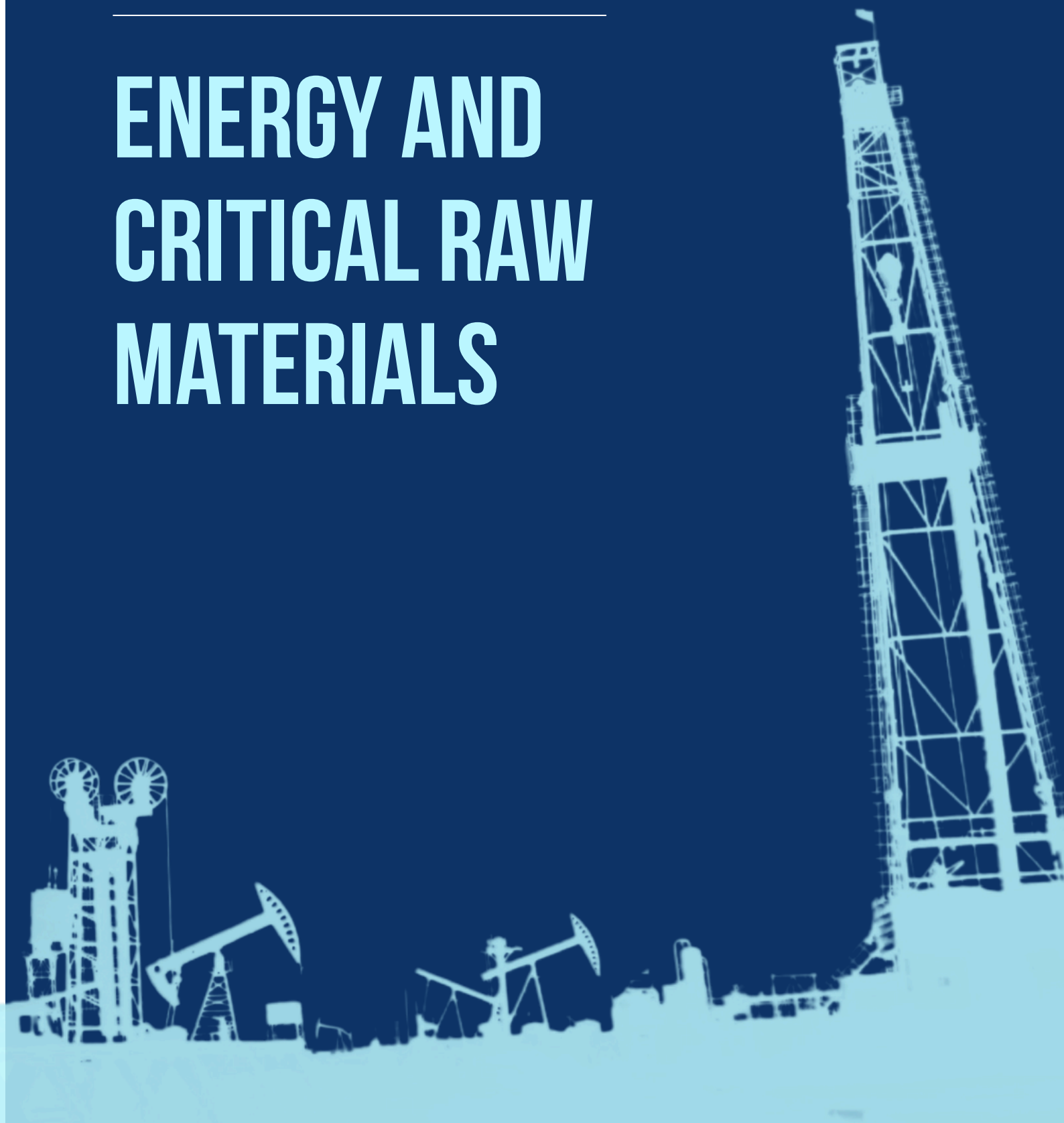
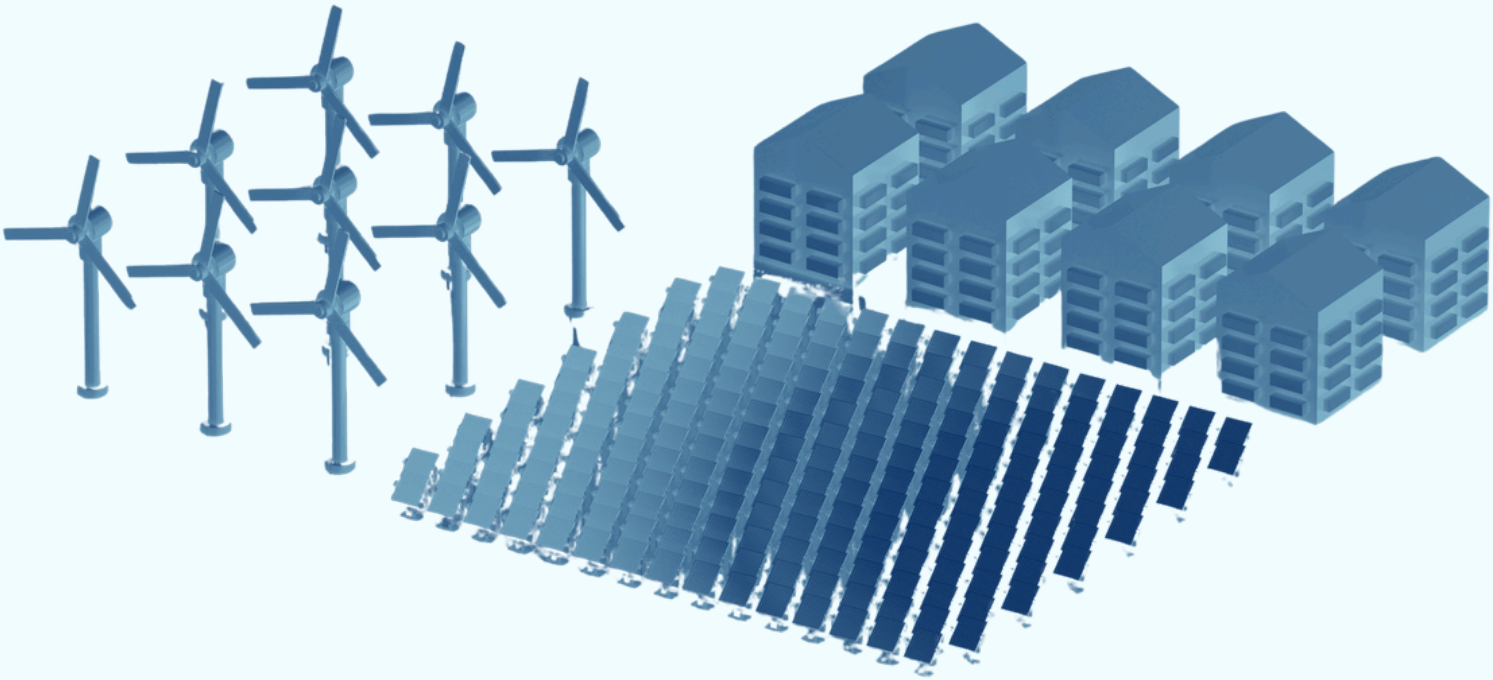
04

ENERGY AND CRITICAL RAW MATERIALS



For decades, Europe's energy policy was a green energy-oriented mission focused on carbon reduction. Right now, that mission has evolved into a model of industrial realism for the purposes of European survival. The biggest strategic change is the shift frombeing clean to prioritising autonomy and independence from foreign actors.

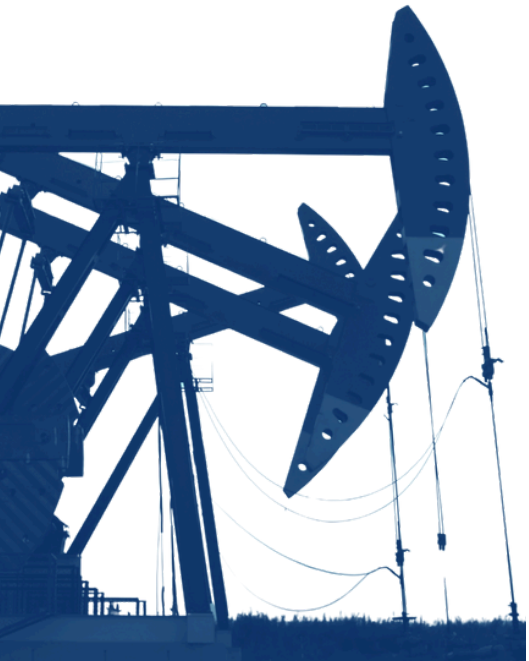
Brussels has stopped treating energy and raw materials as mere global commodities and instead views them as national security assets that are essential for energy security in difficult times. For businesses, this signals that European supply chains are growing in demand and that they will likely be incentivised by the EU to reduce the reliance on the global supply chains.



THE RESOURCEEU ACTION PLAN

While oil and gas were essential materials in the past century, often called the “black gold”, the term now belongs to lithium, cobalt, and rare earth minerals. In December 2025, the Commission adopted RESourceEU, the practical implementation act behind the Regulation on Critical Raw Materials. According to it, the EU must extract 10%, process 40%, and recycle 25% of its strategic raw materials domestically by 2030. Additionally, no more than 65% of any material can come from a single country outside EU – a direct move to reduce the reliance on China.

RESourceEU also introduces a new central watchtower whose role will be to provide market intelligence and aggregate demand. Similar to the idea of the joint purchase of vaccines, the EU will now help companies buy raw materials as a unified single bloc to lower prices and stabilise supply. Another key provision is the restriction on the export of scraps, especially permanent magnets and aluminum. This limitation will go into effect by mid-2026. The EU aims to retain waste within Europe and require businesses to recycle domestically rather than selling to the processors in third countries.



> ***ACCORDING TO RESOURCEEU, THE EU MUST EXTRACT 10%, PROCESS 40%, AND RECYCLE 25% OF ITS STRATEGIC RAW MATERIALS DOMESTICALLY BY 2030.***

THE CLEAN ENERGY INVESTMENT STRATEGY

In March 2026, the Commission unveiled its Clean Energy Investment Strategy, supported by 75 billion euro in financing from the European Investment Bank. This tool for subsidies has the potential to change the outlook for European business. The most significant novelty is the **"Made in EU"** requirement that is part of the proposed Industrial Accelerator Act. If a project aspires to access public funding for products such as batteries or wind turbines, it must prove that a significant portion of the technology was manufactured either in the EU or Norway, Iceland, and Liechtenstein, which are considered trusted partner countries.

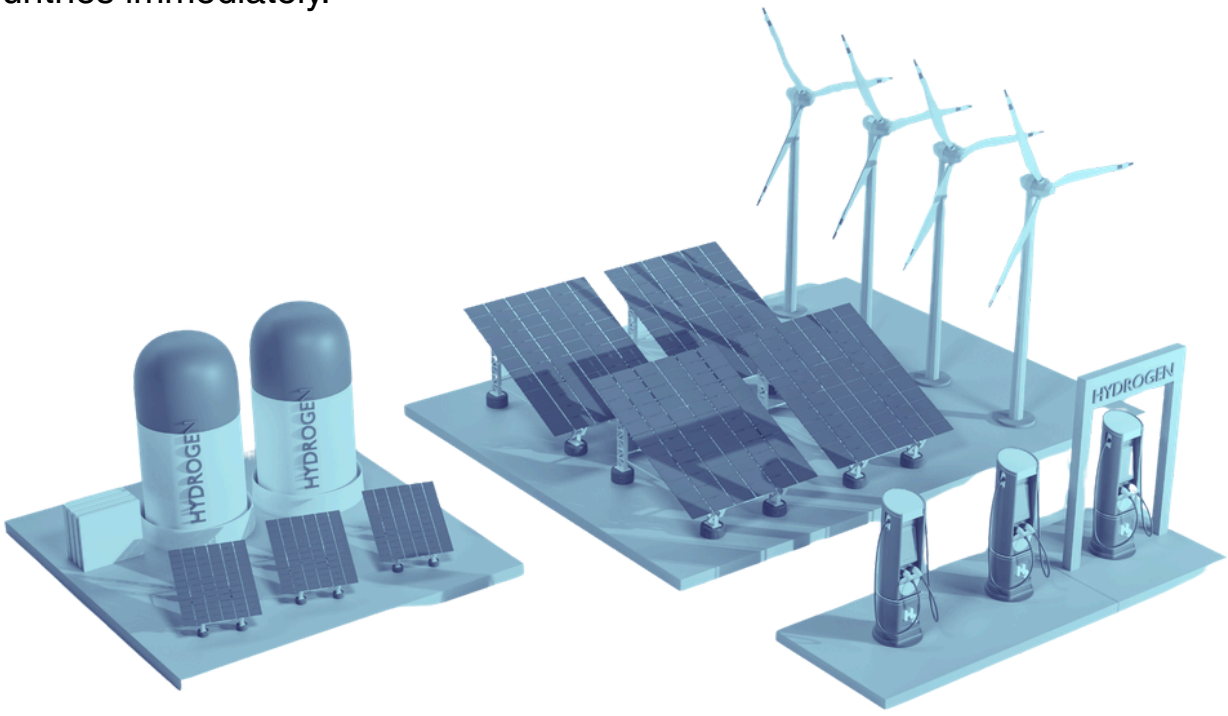
The IAA also creates an advantage for green materials: a project must meet a specific percentage of the materials produced using clean energy or recycled methods to qualify for public funding. For steel and aluminum, at least 25% of the product needs to meet strict eco-friendly standards, whereas the threshold for concrete is set at 5% – as producing carbon-friendly concrete is significantly harder and financially demanding than steel. For electric vehicles, 70% of battery components will need to be EU-made.

THE MOST SIGNIFICANT NOVELTY IS THE "MADE IN EU" REQUIREMENT THAT IS PART OF THE PROPOSED INDUSTRIAL ACCELERATOR ACT.

HYDROGEN

Many countries were announcing national hydrogen strategies, and the European Union has set an ambitious target of 10 million tons for domestic production by 2030. Companies were releasing memorandums of understanding for electrolyser plants over the past couple of years, however only a small amount of those projects had the actual funding secured. Most of the investors now demand a firm offtake agreement – proof that a specific customer has signed a ten-year contract to buy hydrogen at a set price.

To be legally labeled as low-carbon, hydrogen now must prove a 70% emission saving compared to fossil fuels. This methodology is now final and offers investors the legal certainty they needed to sign the ten-year purchase agreements. However, the green premium is higher than it was expected to be, and it has forced the corporate subjects to move away from standalone projects and toward hydrogen valleys. Hence, instead of building a countrywide pipeline, companies can now build the hydrogen plant next to the factories that use them. This physical connectivity helps avoid massive cost of building a pipeline network spanning multiple countries immediately.



THE NEXT MONTHS

The Internal Market Emergency and Resilience Act will become fully applicable in May 2026. In the event of the global crisis, such a sudden shortage of the graphite needed for batteries or the chips essential for building cars, European companies were left to compete on the global market alone and were often outbid by larger players. With a new regulation in place, the European Commission has the legal authority to step in during a crisis and legally mandate that industrial orders that are vital for Europe's security are moved to the front of the queue. For the business, this can be a double-edged sword: if a company is deemed a critical provider, it will offer a sense of safety net, but the standard commercial contracts could be legally paused if a higher-priority emergency arises.

In July 2026,
a major shift is expected in the metals market as the EU plans to reduce the tariff-free import volumes and simultaneously raise the tariff on over-quota steel from 25% to 50%. This policy aims to prevent market saturation of high-pollution imports. If a business relies on the lowest-priced steel available from overseas, the cost will most likely grow significantly. On the other hand, if a company has already switched to European suppliers, it will be in a more stable and competitive position as the rivals will face extra tariffs.

In September 2026,
the EU will finalise its second list of strategic projects under Critical Raw Materials Act, where the companies can expect a reduction in administrative burden. In most cases, opening a new mine or a mineral processing plant in Europe is a bureaucratic challenge taking up to a decade of permits, approvals and court proceedings. Projects on this strategic list will get preferential treatment. By law, a new mine must receive its final approval within 27 months, and a processing plant within just 15 months. A new procedure effectively bypasses years of local administrative back-and-forth. For investors and industrial firms, this translates into a clear, fast-tracked timeline for launching new strategic projects and integrating raw materials into the supply chain.

THE PATH TO COMPLIANCE

Businesses can start preparing for the changes by conducting an audit for the compliance with the new “Made in EU” standards. If a business relies on public tenders or EU subsidies, the “high-risk” components should be reconsidered. Even though it might be fully functional, a product that lacks trust will soon become ineligible for European funding. Under the Industrial Accelerator Act, all Member States must establish a single digital point of contact for industrial permits. If a company’s expansion project is stalled in local bureaucracy, the new EU-mandated acceleration timelines that force a timely decision can provide relief.

It is also advisable to secure secondary raw materials. With export bans on scrap metal and magnets approaching soon, prices for recycled materials within Europe may stabilise while global prices spike. Securing long-term contracts with European recyclers now is a good move to mitigate possible volatility in the future. Companies that align their supply chains with "Made in EU" and low-carbon standards will be more successful with placing their products on a market, and are likely to be protected by a growing layer of strategic tariffs and subsidies.

05

BIOTECH AND PHARMA

BUILDING THE EUROPEAN HEALTH UNION

The European pharmaceutical and biotechnology field this year is undergoing one of the most significant transformations in several decades. For years, the EU has been encountered with an innovation-access paradox. In other words, the Old Continent was home to first class research, but it was falling behind in market speed and equal patient access. As of now, the legislation is becoming clearer. With the formal publication of the Pharma Package texts in March 2026 and the unveiling of the Biotech Act, Brussels is aiming to achieve a “health union” by further integrating local markets. This model attempts to trade off shorter baseline protection periods for regulatory speed and innovation bonuses.

THE PHARMACEUTICAL PACKAGE AND NEW INCENTIVES

The final texts of the Pharma package represent a rewrite of the market's rules of conduct. The core philosophy has shifted from protection to conditional rewards. Firstly, standard regulatory data protection has been changed to 8 years: it is now a baseline number. Companies can earn extensions, under some circumstances reaching up to 12 years, if they meet specific Union interests, such as launching the product in all 27 Member States, addressing an unmet medical need, or conducting comparative clinical trials. Additionally, to combat antimicrobial resistance, the EU has introduced a contentious tool: the Exclusivity Voucher. Developers of priority antibiotics can receive a 12-month extension of data exclusivity under new rules, which they can either use for another product in their portfolio or sell to another company. For major pharmaceutical market players, these vouchers might become a significant new asset class in future M&A negotiations.

Another novelty is the recognition of “breakthrough” orphan medicines, which are now eligible to receive 11 years of market exclusivity, compared with 9 years for standard orphan drugs. This way, the EU attempts to incentivise innovators that use a brand-new mechanism to treat a disease rather than manufacturers of refinement drugs that are similar to those already available on the market. In the past, many companies spent their budgets making the latter as they were regarded as safer investments. The new rules are made to change that conception. By offering much longer protection period and bigger bonuses to new pharmaceutical breakthroughs, the EU is making it more profitable for a company to develop entirely new cures, rather than simply releasing another version of existing medicine.

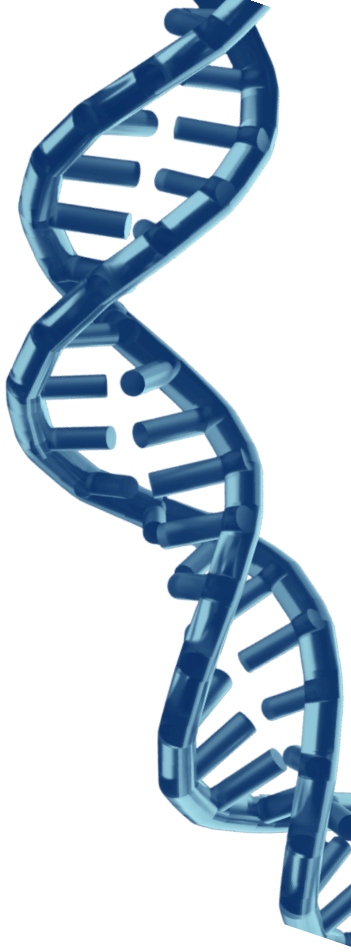
THE BIOTECH ACT

While the Pharma Package fixes the old rules, the Biotech Act unveiled in December last year and the upcoming Biotech Act II – expected in the Q3 2026 – are designed to build new industrial infrastructure required for scaling biomanufacturing.Building up on both Letta and Draghi reports, the Commission aims to rejuvenate EU biotech industry from its decadence – when 66 out of 67 companies chose to list their IPO outside EU in the past 6 years – into a competitive firepower.

To achieve this, much like the strategic projects in other critical sectors, specific biotech initiatives can now apply for strategic status which gives them additional regulatory benefits. This status could grant them a fast-tracked permitting process at a single point of contact in the administration, cutting through the red tape of all of 27 member states. The Act proposes a 12-month extension to Supplementary Protection Certificates for biotech-derived and advanced therapy medicinal products, a move which was considered a major win for the industry players. This is expected to provide a critical buffer against the time lost during complex manufacturing and trial phases. The Act slashes the authorisation timeline for multinational clinical trials from 106 to 75 days and goes as low as 47 days for low-risk trials. The introduction of a Single Core Dossier means that sponsors operating across all Member States can now bypass the need for 27 versions of filing paperwork.

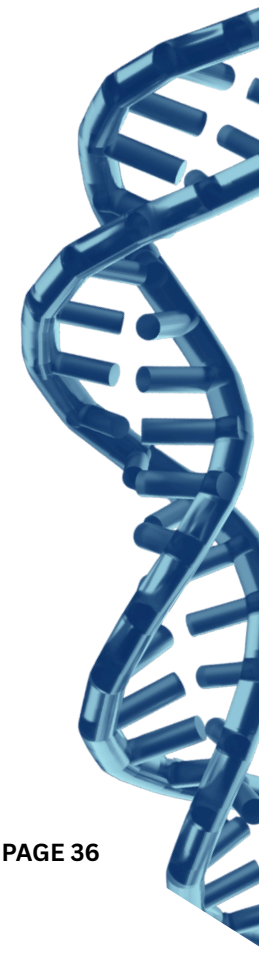
THE ACT PROPOSES A 12-MONTH EXTENSION TO SUPPLEMENTARY PROTECTION CERTIFICATES FOR BIOTECH-DERIVED AND ADVANCED THERAPY MEDICINAL PRODUCTS.

DATA AND INFRASTRUCTURE



The European Health Data Space Regulation, which entered into force in 2025, is transitioning into implementation phase in 2026. The EHDS establishes a unified digital framework that consists of two components: Primary and Secondary Use. The former regulates the exchange of medical records for direct patient treatment. For businesses, the Primary Use is less important in comparison to the massive opportunities in Secondary Use, which will enable the companies to look at batches of anonymous data points that they can use to find patterns and further incorporate them to develop new drugs or train AI models. Until now, if a biotech company wanted to train an AI assistant to spot cancer, they had to ask every single hospital for data. The process was time consuming and even at ties redundant. Under the EHDS, companies now have a legal way to request access to massive cross-border sets of health data. To protect patients, the data is anonymous, and names and addresses are stripped away. The industry players will get the medical insights without the personal identities, which might turn Europe into the one of the most attractive places in the world to train medical AI as the scope of available data is expected to be massive and diverse.

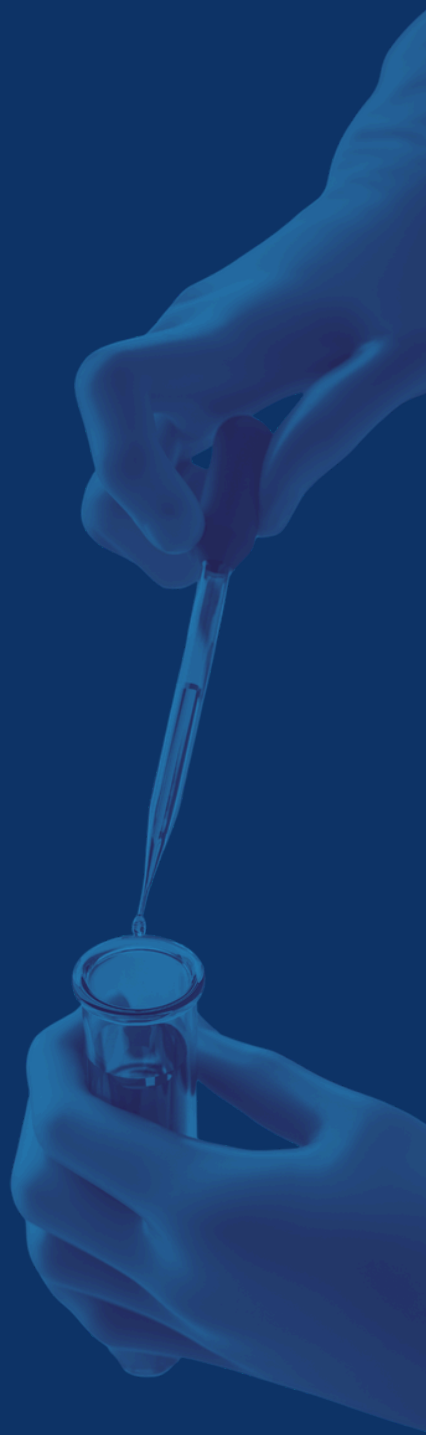
Developing a new medical tool normally takes several years and significant financial committment (often millions of euros), with the constant fear that all nesessary permits might not be granted at the end. The Biotech Act introduces “regulatory sandboxes” to solve this problem. A sandbox is a safe space where a company can test a new idea, such as an AI-driven diagnostic app, under the watchful eye of regulators while still building the app. Instead of waiting a decade for final approval, companies can get proactive feedback in the process. Regulators will give their thoughts on the project in real-time as it might significantly lower the risk of failing at the finish line and help corporations get their product to patients much faster.



THE IMMEDIATE HORIZON

The European Medical Agency will launch its Implementation Gateway, a digital platform providing technical guidance for the full application of the new Pharma rules in the Q2 of 2026. Companies can begin stress-testing their portfolios now, e.g.see whether the drug is launched across all member states if the goal is to get the full 12 years of data protection. Another item to keep a close eye on is the proposal of Biotech Act II. While the first part of the Biotech package is focused on health, Biotech II is expected to expand these fast-track rules to similar areas, such as agri-biotech, energy-biotech, or defence-biotech.

Additionally, until the end of the year, the Commission is expected to publish the first list of critical medicines under the proposed Critical Medicines Act. If a company's product is included, they can expect stricter obligations related to the security of the supply chain. For instance, pharmaceutical players might be legally required to always keep several months of extra stock in EU warehouses or report every roadblock in the supply chain to European authorities. To ease the financial burden imposed by these rules, the EU offers compensation through joint procurement between Member States, the government will award big contracts guaranteeing predictable multi-year revenue. For critical medicines, the EU will not purchase the cheapest offer, but instead will be guided by the "most economically advantageous tender", meaning they will pick a company that might even be more expensive as long as the production is set in Europe or has a better security of supply.



THE EXPECTATION FOR MARKET PLAYERS

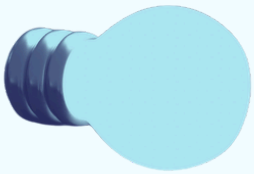
In 2026, the biotech and pharmaceutical sectors are moving away from being automatically eligible for protection towards a system where that protection will need to be earned. The requirement to launch in all 27 Member States may impose additional burden for some companies. Middle-market firms should consider partnering with local distributors early to ensure they don't miss out on the extensions that could make a project more profitable. With Biotech II arriving this fall, corporations should evaluate whether their technologies have applications beyond healthcare, such as in bio-based materials or industrial enzymes. The funding pools for industrial biotech are often less popular than those for traditional pharmaceuticals. Lastly, the new Substances of Human Origin Regulation (nearing its 2027 application) places higher personal responsibility on management for the quality and safety of blood, cell, and tissue products.

The 2026 regulatory environment will reward speed and transparency. The companies that will thrive are likely those that stop viewing compliance as a mere legal cost and start using the new fast-track strategic labels as a competitive tool to reach the market before their global rivals do the same.

“WITH BIOTECH II ARRIVING THIS FALL, CORPORATIONS SHOULD EVALUATE WHETHER THEIR TECHNOLOGIES HAVE APPLICATIONS BEYOND HEALTHCARE, SUCH AS IN BIO-BASED MATERIALS OR INDUSTRIAL ENZYMES.

06

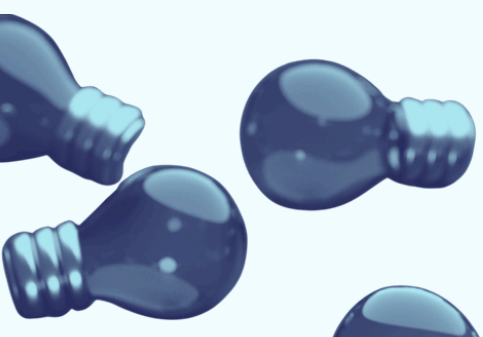
AUDIOVISUAL INDUSTRY & INTELLECTUAL PROPERTY



The definition of ownership is shifting from physical to algorithmic in the modern age, both in Europe and globally. The legal focus is slowly shifting from simply protecting an idea to demonstrating how that idea was developed. The industry is navigating a landmark collision between traditional copyright and generative AI, alongside a broader redefinition of how technology is shared across borders.

One of the major developments has been the European Parliament's Resolution on Copyright and AI, published in March 2026. Resolution itself is not a legally binding document – however, it does hold significant value as it determines topics of discussion and sets the legislative agenda for the European Commission. The original 2019 Copyright Directive was more focused on large digital platforms, while the new rules in 2026 will primarily address the training data behind AI. One of the key provisions of the Resolution is that developers can no longer claim that training their models in the US or Asia exempts them from EU law. If an AI tool is accessible to a user in Bratislava or Marseille, the company must comply with the EU copyright transparency, regardless of where the server is located.

Simultaneously, the AI Act's "sufficiently detailed summary" requirement is likely to be upgraded. Regulators now expect to receive an itemised listof copyrighted works used for model training. This means that creators will be able to see whether their book, song, photo, article, or other artwork was used to build a specific AI model. Lastly, a new proposal for the EU Intellectual Property Office to serve as a central hub for creators to opt out from their work used in AI training purposes. Instead of a photographer notifying dozens AI companies individually, they could register a single legally binding machine-readable signal at the EUIPO.



THE TECHNOLOGY TRANSFER RESET

From May 2026, the new Technology Transfer Block Exemption Regulation takes effect – a set of rules on know-how sharing that allow companies to enter into licensing agreements without violating EU competition law.

The core concept of TTBER is the so-called safe harbour — a guaranteed safety zone where a licensing agreement of technology rights – such as patents, know-hows, or software copyright – is automatically considered legal and helpful to the economy, and will not be challenged by antitrust regulators. The core concept of TTBER is the so-called safe harbour — a guaranteed safety zone where a licensing agreement of technology rights – such as patents, know-hows, or software copyright– is automatically considered legal and helpful to the economy, and will not be challenged by antitrust regulators, although the “hardcore” violations such as price fixing instantly break that guarantee. Traditionally, when two companies, especially competitors, sign a contract to share technology or patents, competition authorities consider the deal a “cartel,” designed to keep prices high or push competitors out of the market. Proving that a deal is pro-innovation rather than anti-competitive can be a long and expensive legal process.

The EU uses a simple mathematical formula to provide businesses with the needed certainty: If two companies that usually compete with each other share technology, their combined market share must be below 20%; for non-competitors this threshold is 30%. If a business stays within these percentages, there is automatic legal protection. There is no need to proactively prove to the EU that a contract is fair, as the law assumes it is beneficial by default. This allows companies to collaborate and share tech quickly without ongoing an antitrust investigation.

The updated version of TTBER adds a three-year grace period. If a company's market share exceeds the limit, it will now have three years (instead of two, as in the current rule) to adjust the contracts before losing its safe harbor status. Lastly, the new regulation will include a set of rules regarding data licensing. The European Union is signaling that data represents more than mere information. In the modern age, data is a foundational industrial component, and if a company can't license the right data, it will struggle to build a final product. Sharing data between companies is usually legally risky as it might resemble information sharing between competitors, which is often problematic under antitrust laws. The new TTBER provides that where firms share the data to produce new goods or services and its market share is under 20% or 30% threshold, the government will not create unnecessary problems, as data licensing falls within the scope of block exemption, provided that it is for the production of contracted goods. This gives companies greater confidence to trade data like any other material.

THE NEW TTBER PROVIDES THAT WHERE FIRMS SHARE THE DATA TO PRODUCE NEW GOODS OR SERVICES AND ITS MARKET SHARE IS UNDER 20% OR 30% THRESHOLD.

STANDARD ESSENTIAL PATENTS AND CRISIS LICENSING

The industry expected a game-changing SEP regulation to manage patents inside the technologies such as 5G or Wi-Fi for years. The EU surprisingly abandoned the specific SEP proposal in late 2025. Instead, the year 2026 marks the beginning of a new phase for Union Compulsory Licensing which entered into force on 19 January, allowing the Commission to authorize “Union-wide” use of patented technologies without owner’s consent in cross-bordered crises, such as pandemic or energy shock. This “emergency button” is most interesting addition to the EU legal landscape. The EU concluded that in an emergency, the continent couldn't afford to let a single patent holder block the production of a vital medicine or a battery component. This creates a strong incentive for patent holders to sign FRAND (fair, reasonable, and non-discriminatory) deals early instead of risking a state-imposed license.

The UCL Regulation is just a specific regime that serves a single purpose, and it is not the SEP regulation the industry was expecting. The new Standard Essential Patent proposal is not expected to start its journey through the legislative procedure during this year, but the business can expect it as soon as 2027.

“THE YEAR 2026 MARKS THE BEGINNING OF A NEW PHASE FOR UNION COMPULSORY LICENSING, ALLOWING THE COMMISSION TO AUTHORIZE “UNION-WIDE” USE OF PATENTED TECHNOLOGIES WITHOUT OWNER’S CONSENT IN CROSS-BORDERED CRISES, SUCH AS PANDEMIC OR ENERGY SHOCK.

OPERATIONAL READINESS IN THE NEW REGULATORY LANDSCAPE

All existing technology transfer agreements should be audited to ensure that they fit the new safe harbour market-share calculations. On 2 August 2026, the transparency obligations under AI Act for GenAI models officially take effect. If a company uses AI to generate content for its clients, it must ensure that it is labeled correctly until that date. By September 2026, the EU is expected to finalise a technical standard for digital watermarking to help the copyright registries identify AI-generated works.

If a company uses AI, it would be advisable to ask the provider for some sort of transparency report. If they can't provide an itemised list of their training data, the user company may be at risk of contributory copyright infringement under the new rules. At the same time, with the new TTBER, a gap analysis that would help identify which contracts might not fit the safe harbour standards anymore can be of help. Finally, if the company is part of the AV industry, such as advertising or film, the implementation of the machine-readable label for any AI-assisted work is already a must. In 2026, denying the knowledge that the work was generated using AI is no longer a valid legal defence.

Altogether, the current year brings new priorities for the intellectual property and audiovisual industries, and it is important to adapt to the new rules and standards in order to stay competitive and stay out of the danger zone of breaching the EU law.

07

THE 28TH REGIME AND THE RISE OF EU INC

If there was a successful founder in Berlin who has built a breakthrough AI diagnostic tool and now wants to expand to neighbouring countries such as France or Austria, it would be rather difficult to do so. In other major economies, such as the United States or China, this would involve a few clicks and a standard contract. In the European Union, however, this means hitting a “legal wall” 27 times. A corporation has to navigate 27 different sets of corporate laws and notary appointments, as well as 27 different labor and tax regimes.

For many businesses, the “cost of Europe” was too high, leading to the infamous Delaware flip where Europe’s best companies would move to the United States just to escape EU’s administrative burden. With the tabling of the EU Inc. proposal in March 2026, these long-standing obstacles are expected to dissolve, replaced by a unified path for pan-European scaling. The European Commission has officially tabled the EU Inc. Legislative Proposal to establish what is known as the 28th Regime.

28TH REGIME 101

The 28th Regime is not a replacement for national laws. Instead, it is a virtual 28th state that exists in the digital cloud of the European Union. It is an optional legal framework. A business owner in Rome can choose to incorporate under Italian law (s.r.l.) or as an EU Inc., technically proposed as the Societas Europaea Unificata. If a company decides to opt in the 28th Regime, they will operate under a single, harmonised rulebook that is recognisd exactly the same way in one part of the continent as it is in the other. It is a legal ID that allows a company to grow across the entire single market without ever having to adapt to the new laws as they enter new member states.

Unified Stock Options

The European Employee Stock Option scheme is arguably the most intriguing part of the proposal. Currently, offering an employee in one Member State stock in a startup of another Member State is a complicated process, both legally and tax-wise. Under EU Inc., stock options follow a different model. The employees are not taxed when they are granted the options, nor when they exercise them. They are only subject to taxes when they eventually sell shares for cash. This change might allow European startups to compete with the larger non-EU companies for highly skilled workforce by providing a simplified path to wealth-sharing that is expected to work across borders.

The Practical Mechanics

EU Inc is the flagship product of this regime. Based on the current proposal, there are several provisions that anyone who wants to open a European company should be aware of. First, founders can incorporate an EU Inc. entirely online via a central EU portal. The target is a setup time of under 48 hours and a cost of less than €100 without mandatory minimum share capital – the company can now be started with as little as 1 euro. This is a procedural mitigation for all companies since the minimum capital in some countries can go as high as 25 000 euros, and the incorporation procedure can take months.

Another benefit for the businesses that the proposal suggests is the rule that once a company submits its ID, articles of association, beneficial ownership data and similar basic documents to the EU central interface, there will be no need to repeatthe process in case of expanding to another country. That new country is legally barred from requesting the same paperwork. Additionally, the 28th Regime is deemed to be friendly towards venture capital. It supports investment instruments like SAFE (Simple Agreements for Future Equity), which are the standard in Silicon Valley but were often not legally regulated areas across Europe.

THE IMPACT OF THE 28TH REGIME AND NEXT STEPS

The 28th Regime is yet another fundamental shift that attempts to address European competitiveness**.** Scaling costs are likely to decrease significantly. This will particularly affect the mid-sized industrial and service-sector companies, as the regime is projected to reduce approximately 30-40% of legal and administrative burden associated with expansion into the new countries. The benefits are mirrored for investors as well. Investors prefer certainty, and the EU Inc. structure aims to signal to global VC funds that the legal basis of the company is standardised and secure, smoothing the way to close series A and B funding rounds.

Another key consideration is the safety net provided by the Regime. The proposal includes a fast-track liquidation process. That means that if a venture doesn't succeed in the market, it can be wound up in six months. This reduces the stigma of failure for risk-averse entrepreneurs and allows them to move on to their next idea faster.

In Q2 of 2026, the European Parliament and the Council will begin the negotiations. The main point of contention will likely be employee participation. Some countries, including Germany and France, will most probably want to ensure that their labor board standards are not weakened by the new EU Inc. corporate form.

The second part of the year is likely to be the most critical for making the 28th regime a reality. Ireland will assume the presidency of the Council, and as a country that often serves as a bridge for global (and especially American) companies to Europe, it might prioritise shaping the deal about the regulation during their term. A final political agreement on the Regulation by the end of the year is not guaranteed but seems probable. Once the regulation is adopted, the first EU Inc. entities are expected to be registered in the EU Central Business Registry in mid-2027.

PREPARING FOR EU INC

For a business that wants to stay up to date with the latest legislation, the current move could be to delay major structural changes while optimising for the new standard. For instance, if a company plans to incorporate new subsidiaries in 2027, it could consider holding off on permanent national structure until the new rules are in place. This might save thousands of euros in notary and translation fees. Alternatively, if a company struggles to attract skilled talent from outside of the Member State, unified stock option rules are something to consider. Likely, it be the first fast-acting change for companies under the new system.

There is an ongoing debate on whether EU Inc. should only be for “innovative startups”, defined as those that prove that their R&D costs have represented at least 10% of the company's total operating costs over the last three years. In plain language, if a company spends a million annually to run, it is only considered an innovative startup if it spends 100,000 euros on research and development. The opinions are split on the topic of whether the EU Inc. should be open to anyone, or only the startups that meet these standards. The rationale for limiting the scheme to a smaller group of companies is that it will be easier to reach an agreement between Member States, but the risk is that many mid-sized firms will be excluded from the 28th regime. A realistic outcome of this dilemma will be a certain middle ground where the EU Inc. form willbe open to everyone with extra features, such as tax breaks or unified stock option schemes, remain reserved for the qualified players.

Regardless of the outcome, the 28th Regime is likely to become one of Europe’s most significant efforts to turn 27 fragmented markets into a single unified market. It is expected to set in motion European scale-up ambitions and could represent a business-friendly regulation, providing market players with more flexibility and opportunities for growth.

FAST-MOVING CONSUMER GOODS

The European FMCG and grocery retail sector enters 2026 confronted with one of the most consequential regulatory realignments of the past decade. Legislative initiatives advancing simultaneously across packaging, sustainability, food safety, health policy and controlled categories are no longer incremental adjustments; they amount to a fundamental transformation of how products are designed, sourced, marketed and sold across the European market. For retailers and suppliers already facing margin pressure, cost inflation, and shifting consumer expectations, regulatory compliance is rapidly transforming from a mere compliance requirement into an integral part of FMCG companies' business strategies in Europe.

COMPLIANCE WITH THE PACKAGING STANDARDS

Packaging, environmental performance and sustainability obligations sit at the centre of FMCG companies next years strategies.

The Packaging and Packaging Waste Regulation, set to enter into force in August 2026, aims to switch fragmented national legislation into harmonised EU-wide rules on sustainability, ensuring that all packaging in the EU can be recycled or reused by 2030. Specifically, the Regulation covers issues of recyclability, minimum recycled content, compostability and chemical safety, including restrictions on substances such as PFAS.

For suppliers, changes to packaging design will become unavoidable, while documentation requirements will expand into formal compliance statements, traceability evidence and full transparency on packaged contents. These requirements are reinforced by the Ecodesign for Sustainable Products Regulation, which from July 2026 prohibits the destruction of unsold consumer goods, forcing companies to rethink how they manage their stock, handle unsold inventory, and organise returns, redistribution, and recycling flows.

Sourcing of High-Risk Commodities

New rules are tightening plastic waste shipments as the EU is gradually enforcing the Deforestation Regulation. Companies will have to perform due diligence and verify geolocation of high-risk commodities like coffee, cocoa, palm oil, soy, and cattle. Retailers, particularly those with extensive store-labelled products, are under greater pressure to ensure integrity of sourcing materials, handling waste and conducting back-of-store operations, pushing sustainability considerations directly into day-to-day commercial decision-making.

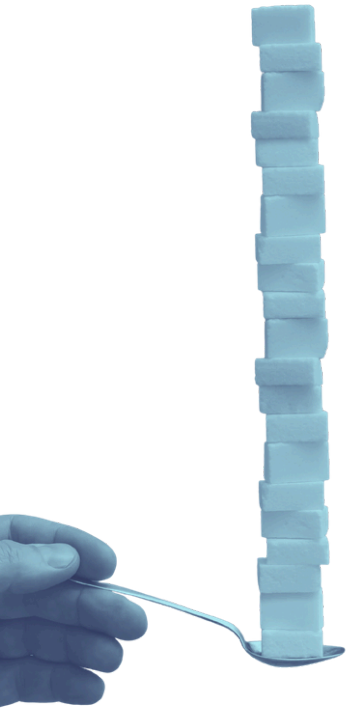
Increasing Food Safety

IIn 2026, food safety and product quality standards are significantly rising. The tightening of criteria for Listeria monocytogenes in ready-to-eat foods, approved by the European Food Safety Agency with EU Regulation 2024/2895 ,elevatesexpectations well beyond manufacturing, extending responsibility across distribution, in-store handling and temperature control. Updates to Maximum Residue Levels will lower the allowed amounts of chemical residue in food, affecting both fresh produce and processed food, Some European countries are also updating their nutrient-profiling systems – the rules that assess food quality based on the quality of ingredients, which means that claims of nutritional value and food quality on packaging will need to be reviewed. For suppliers, this translates into higher testing frequencies, stronger validation requirements and, in some cases, reformulation where residues, additives or food-contact materials no longer comply. Retailers are more exposed across the entire ready-to-eat supply chain, particularly within private-label portfolios, where non-compliance may result in products being removed or replaced with compliant alternatives.

Food for Thought

Health-driven intervention is especially pronounced in products intended for youth consumption. National bans on energy drink sales to minors, alongside tightened advertising restrictions for high-fat, salt and sugar products and the introduction of sugar-related excise taxes, underline a clear European shift toward more regulated diet and health policy. These measures push companies to revise their product recipes, make managing products across borders more complex, and constrain traditional marketing channels. For retailers, age-verification requirements for energy drinks increasingly mirror those applied to alcohol and tobacco, reshaping store operations, online sales flows and merchandising strategies, while expectations grow for retailers to actively promote healthier alternatives.

EU food waste reduction requirements go hand in hand with ensuring that sustainability policies are measurable and achievable. Waste Framework Directive requires a 30 percent per-capita reduction by 2030, placing retailers and foodservice operators at the centre of delivery, elevating the importance of donation programmes, demand forecasting and waste-prevention initiatives. Suppliers are being more involved in these efforts by improving packaging efficiency, updating date-labelling practice, and building collaboration with retail partners to reduce waste across the value chain. **Performance on waste reduction is set to become a core metric in sustainability reporting, with direct implications for reputational risk and commercial relationships.**



Tightening the Rules around Alcohol and Nicotine

Regulatory complexity deepened further in alcohol, tobacco and nicotine categories, where national measures are now reinforced by a highly contested EU-level policy debate. In April 2026, Austria increased taxes and introduced licensing requirements for nicotine pouches and e-liquids, while Ireland introduced a requirement of tobacco-style health warnings on alcohol packaging starting from May 2026. This marks a significant escalation in the regulation of a historically distinct category. These national initiatives coincide with the revision of the Tobacco Products Directive, informed by the European Commission's first comprehensive study on the health effects of alternative tobacco products such as e-cigarettes, heated tobacco and nicotine pouches.

Although formally presented as an evaluation exercise, the process is already shaping expectations of tighter regulation, with the Commission signalling a precautionary stance and internal scrutiny suggesting that forward-looking measures are being embedded early.
The debate on how to regulate tobacco and alternative nicotine products is politically entangled with parallel negotiations on the Tobacco Excise Tax Directive and the Tobacco Excise Duty Own Resource, which policymakers in Brussels view as critical to financing the EU budget. Divergent national interests, unresolved scientific questions and the requirement for unanimity have stalled progress, creating uncertainty over both regulatory direction and fiscal outcomes.

For suppliers, the convergence of health regulation and tax policy raises compliance costs, tightens pricing flexibility and increases the need for regulatory-affairs capacity. Retailers must prepare for evolving licensing regimes, category restructuring and enhanced staff training as regulatory expectations at the point of sale continue to rise.

Taken together, the 2026 regulatory outlook confirms that legislation is no longer a peripheral constraint on the FMCG sector, but a central driver of how companies operate, compete, and scale. Businesses that integrate regulatory foresight into product development, sourcing and category management will be best positioned to manage risk and capture opportunity in Europe's increasingly strict regulatory environment.

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