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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

establishing a framework of measures for strengthening the Union innovation ecosystem and amending Regulation (EU) 2017/1001 (European Innovation Act)

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(Text with EEA relevance)

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EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

1.1. Reasons for and objectives of the proposal

The European Union (EU) is a global leader in scientific research, producing a significant share of the world's high-quality scientific output. However, this strength does not translate into a commensurate level of innovation performance and commercial success within the Single Market. Innovative ideas developed in Europe too often fail to reach the market, scale across borders, or generate new growth sectors. As a result, the Union captures only a limited share of the economic and societal value generated by its scientific and technological strengths, constraining the emergence of globally competitive firms and long-term productivity growth.

Enhancing the conditions for the development, commercialisation, and scale-up of innovative solutions has become a central priority of the Commission's policy agenda for 2024–2029, which places research and innovation at the core of Europe's competitiveness and sustainable prosperity. In this context, the proposed Regulation contributes to the implementation of the EU Startup and Scaleup Strategy[1] and responds to the mandate set out in the Mission Letter of Commissioner Zaharieva develop a framework facilitating the testing, financing and scaling of innovative solutions in the EU.

Over the past two decades, the EU's economic growth has lagged that of other major economies, notably the United States (US) and China, with a widening difference in GDP levels. A key driver of this divergence is weaker productivity growth in the EU. As research and innovation account for a substantial share of productivity gains, the Union's ability to translate knowledge into marketable innovations is a critical determinant of its long-term competitiveness and prosperity.

The underlying challenge lies in structural barriers along the innovation lifecycle. While the EU performs strongly in early-stage research, it faces persistent difficulties in the transition from research results to market-ready products and scalable businesses. Innovative firms encounter two critical bottlenecks: a pre-commercialisation gap, where projects remain too risky or fragmented to attract private investment, and a scaling gap, where firms struggle to expand due to financial, regulatory and market constraints. These bottlenecks reduce incentives for investment and limit the emergence of new innovative firms and sectors.

Over the past years, the Union has taken significant steps to address these challenges. EU funding programmes, such as Horizon Europe, the Recovery and Resilience Facility, the Innovation Fund, the Digital Europe Programme, and InvestEU, as well as initiatives aimed at deepening capital markets and strengthening the European Research Area, have contributed to improving framework conditions for innovation.

However, despite this progress, **important barriers and disparities between Member States persist**, particularly in the transition from research to market deployment.

First, markets for R&D procurement, including pre-commercial procurement, remain underdeveloped because of the lack of a clear legal framework. The EU Public

[1] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, The EU Startup And Scaleup Strategy Choose Europe To Start And Scale, COM/2025/270final, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025DC0270

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Procurement Directives cover R&D services only where both of the following conditions are met:

- the benefits accrue exclusively to the public buyer for use in its own affairs; and
- the public buyer wholly remunerates the service.

As a result, a substantial share of R&D procurement, including pre-commercial procurement, falls outside their scope. Since the Commission clarified the concept of pre-commercial procurement in 2007 in its Communication[2], there has been an increase in these types of R&D procurements and success cases show that strategic use of this instrument enables the EU to regain leadership and strategic autonomy in high-tech markets. However, overall, across the EU, the progress in raising investment levels is still too slow and fragmented. Key reasons are that the absence of harmonised rules has contributed to divergent practices across Member States, legal uncertainty, and limited use of joint cross-border R&D procurement, which is often necessary to achieve the financial critical mass required for the development of innovative technologies. Moreover, the proposed revision of the EU public procurement framework, the Public Procurement Act, proposes to exclude all forms of R&D procurement.

Such public procurements of R&D are vital to create innovative solutions that can improve the quality and efficiency of public services, address societal challenges and build sufficient industrial capacity for innovative solutions and technologies in the EU to safeguard EU strategic autonomy. Other leading economies in the world are investing 5 to 8 times more in public procurement of R&D than the EU[3]. Raising public investments in R&D procurement in the EU from 0,6% to 3% of total public procurement or from €17,28Bn to €86,4Bn, would help the EU raise public R&D investments with 0,4% of GDP. Given that this could raise an equal additional amount of private investments in R&D, total investments in R&D in the EU could thus rise from 2,2% to 3% of GDP[4].

Second, insufficient clarity and comparability in the valuation and monetisation of intellectual property (IP) continue to hinder the commercialisation of research and innovation results. Innovation is now largely driven by intangible assets, with over 90% of corporate value in certain leading firms coming from intellectual property. Yet in the EU, IP is still rarely used as collateral in financing. Because financial institutions in the EU still focus mostly on tangible assets and traditional accounting, IP-rich companies struggle to secure financing. As a result, EU startups raise around 50% less capital than US peers by their tenth year. This mismatch has created a major growth financing gap for asset-light, innovative firms, estimated at up to EUR 18 billion per year.[5] One of the key reasons explaining the lack of IP-back financing in the EU is the absence of a harmonised methodology for valuing intellectual property assets. This created divergent conditions across Member States for the

[2] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 'Pre-commercial Procurement: Driving innovation to ensure sustainable high quality public services in Europe', 14.12.2007, COM(2007) 799 final

[3] The EU spends 0,6% of public procurement on R&D, the US 3,5% and South Korea 5%. Raising investments in the EU to 3% of total public procurement on R&D would generate additional public R&D investments equalling 0,5% of GDP - EU wide benchmarking of innovation procurement policy frameworks and investments

[4] In 2023, public and private investments into R&D was 2,2% of GDP in the EU, compared to 3,3% in Japan, 3,46% in the US, 4,93% in South Korea - Science, Research and Innovation Performance (SRIP) report, 2024 edition, European Commission

[5] European Investment Bank. (2025). Investment Report 2024/2025: Innovation, integration and simplification in Europe

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use of such assets in company financing, including as collateral for debt financing and for their consideration in equity investment and other financing decisions. Other key reasons are the lack of a mature EU-wide secondary market for intangible assets and a lack of skills regarding IP-backed financing among financial institutions and innovative startups. This undermines companies' access to capital within the Single Market, impeding their cross-border growth and investment. And making EU companies less successful than companies from other jurisdictions, such as the US, China and South Korea, at scaling and commercialising innovation, especially in deep tech and breakthrough sectors.

Addressing these two barriers through this proposal could thus have a sizeable impact on improving the functioning of the Single Market for R&D investments and commercialising IP assets. Against this background, this proposal delivers on President von der Leyen's 2024-2027 Commission Political Guidelines that set priorities to put research and innovation at the heart of our economy. The **European Innovation Act** was announced in the EU Startup and Scaleup Strategy and in the Competitiveness Compass for the EU as one of the key initiatives to strengthen the EU's innovation ecosystem and enhance its ability to compete globally.

The general objective of this initiative is to improve the functioning of the Single Market for innovation by reducing structural barriers to bring innovative solutions to the market, thereby speeding up their commercialisation in the EU. This objective contributes directly to the Union's broader priorities of strengthening competitiveness, fostering sustainable economic growth, and enhancing technological sovereignty.

To achieve this, the proposal pursues a set of specific objectives. These include strengthening the role of public procurement as a driver of innovation and enhancing the valuation, commercialisation and use of IP.

The European Innovation Act aims to achieve these objectives by:

- creating a harmonised framework at Union level for R&D procurement, including pre-commercial procurement; and
- mandating the creation of a competence centre on IP-backed finance at Union level as part of the European Union Intellectual Property Office (EUIPO), an Union-wide framework for IP valuation and a Union-wide IP marketplace for commercialising IP.

By addressing these challenges in a coherent and targeted manner, the proposed Regulation seeks to ensure that innovative ideas developed in Europe can more effectively progress from research to market, scale across borders, and contribute to the Union's long-term competitiveness and prosperity.

1.2. Consistency with existing policy provisions in the policy area

There is currently no comprehensive Union legislative framework specifically addressing the cross-cutting barriers affecting the development, testing and scale-up of innovative solutions across the Single Market. Existing Union policies in the area of research and innovation primarily focus on supporting knowledge creation, fostering collaboration and providing funding for research and innovation activities, while only partially addressing the framework conditions governing the transition from research to market.

The proposed Regulation complements these existing initiatives by targeting the remaining bottlenecks along the innovation lifecycle, in particular those related to the use of R&D procurement, and commercialisation and use of IP in financing of innovative companies.

In this context, the most relevant Union policy provisions in the field of research and innovation include:

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The European Research Area (ERA) incentivises and structurally support cross-border research and development (R&D) collaboration and researcher mobility, primarily targeting the early stages of the research and innovation lifecycle. It is implemented in part through Union programmes such as Horizon Europe, which provide funding for collaborative research, mobility schemes and research infrastructures. In parallel, the ERA Forum serves as a soft coordination tool through which Member States align national research policies, priorities and reforms.

Union funding programmes provide substantial financial support to research and innovation activities across the different stages of the innovation lifecycle. In particular, programmes such as Horizon Europe, including the European Innovation Council, as well as InvestEU, Digital Europe Programme, the European Defence Fund, the Cohesion Policy Funds and the Innovation Fund support the development, demonstration and, to some extent, the scale-up of innovative solutions through grants, blended finance, risk-sharing mechanisms and via support for R&D procurements. Without prejudging the next Multiannual Financial Framework (MFF) and the implementation of future EU funding programmes, the next MFF may strengthen this financial support by enhancing the Union's capacity to mobilise public and private investment in innovation and strategic technologies. The proposed Regulation is consistent with these Union programmes as it does not propose any funding measures but will reinforce the legal framework conditions for innovation across the Member States, which can complement and contribute to improve the impact of these Union funding programmes in a number of ways:

- Several of these Union funding programmes provide support to public buyers to conduct R&D procurement. These experiences have also highlighted a remaining lack of confidence of public buyers in starting pre-commercial procurements due to the absence of a clear EU wide legal framework for pre-commercial procurements, and they have also highlighted the extra effort and time it takes for public buyers to setup joint cross-border pre-commercial procurements due to fragmentation of national procurement rules across Member States. The proposed Regulation helps address this issue by establishing common rules for implementing R&D procurement, including pre-commercial procurement, and a harmonised framework for joint cross-border R&D procurement, including pre-commercial procurement.
- Some of these Union funding programmes support innovators in trying to commercialise their IP or to use their intellectual property rights as collateral to obtain financial investments. These experiences have highlighted that innovators face issues in finding the right parties that are interested in buying or licensing their IP and getting good value out of their IP for obtaining financial investments due to a knowledge gap and the lack of a Union-wide accepted valuation framework and the lack of a Union-wide marketplace for IP rights. The proposed Regulation helps address this issue by extending the mandate of the European Union Intellectual Property Office to establish a competence centre for IP-backed finance, a common framework for the valuation of IP and a Union-wide marketplace for the commercialisation of IP rights.

It follows that the proposed Regulation is consistent with existing Union policy provisions in the field of research and innovation by complementing existing funding programmes with a coherent framework for R&D procurement and with new tasks for European Union Intellectual Property Office that will help innovators obtain IP-backed finance.

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1.3. Consistency with other Union policies

The proposed Regulation is a cross-sector initiative aiming to deliver a Union-wide level playing field for innovators across all sectors, rather than focusing on specific application sectors, technology fields or industries. Its measures are horizontal by design and address structural barriers across Member States that affect innovation-intensive activities.

The proposed Regulation complements the forthcoming 28th Regime corporate legal framework – EU Inc., providing a harmonised framework for companies operating across the Union. The proposal also complements the reforms under the Savings and Investments Union, which aim to deepen the Union capital markets and channel more private savings into equity, venture capital and scale-up financing, thereby improving access to finance for innovative firms. Despite the expected progress in regulatory harmonisation under the European Commission's EU Inc. initiative and related omnibus legislation that aims to make it easier for innovators to set up and operate a business across the Union, significant fragmentation persists in how companies can navigate the innovation lifecycle. This fragmentation risks hampering companies to bring innovative solutions to the market which could limit the growth potential of companies that are set up under the harmonised EU Inc. framework. In other words, while the 28th Regime aims to facilitate setting up and operating a business across the Union, the proposed Regulation is designed to address further bottlenecks in the innovation lifecycle, ensuring that companies can develop and market their innovations more easily across the Single Market.

Similarly, despite the expected progress under the Savings and Investments Union in deepening the Union capital markets and mobilising private investment, significant constraints persist in other parts of the innovation lifecycle. In particular, barriers related to the development, testing, valuation and early adoption of innovative solutions continue to limit the pipeline of investment-ready projects. As a result, while the Savings and Investments Union aims to improve access to finance and support the scale-up of innovative companies, the proposed Regulation removes bottlenecks that hamper innovative ideas to attract IP-backed finance and helps innovators fully benefit from improved capital market integration.

The proposed Regulation also complements sectoral initiatives, such as the existing Critical Medicines Act, the Cloud and AI Development Act, the Biotech I Act and the forthcoming Advanced Materials Act and Biotech II Act, targeting strategic sectors or technologies and aim to strengthen the Union's position as a high-tech powerhouse. While these initiatives provide tailored, sector-specific approaches where needed, the European Innovation Act addresses the cross-cutting gaps affecting innovation across sectors and across different technology fields. It does so without prejudging or interfering with sector-specific frameworks, thereby ensuring coherence across the overall Union innovation policy landscape.

Finally, the proposed Regulation also complements the EU Public Procurement Directives and their proposed revision through the Public Procurement Act (PPA). The EU Public Procurement Directives exclude pre-commercial procurement, while certain R&D service procurements still fall within their scope and the procurement of R&D is a mandatory element of the innovation partnership procedure. By contrast, the PPA proposal excludes all forms of R&D services procurement and removes also the procurement of R&D as a mandatory component from the current innovation partnership procedure by replacing this with a new innovation challenge procedure having as mandatory elements a testing phase and a phase for procuring commercial deployment, which can include volumes of innovative solutions.

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2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

2.1. Legal basis

The legal basis for the proposed Regulation is Article 114 of the Treaty on the Functioning of the European Union, which allows the Union to adopt harmonisation measures to ensure the proper functioning of the internal market. This is needed to remove cross-border regulatory and structural barriers that hinder research, development, testing, commercialisation and diffusion of innovative solutions across Member States and hamper achieving the Single Market objectives.

The choice of the legal basis is supported by the fact that the problems addressed by the proposal produce a direct and demonstrable impact on the proper functioning of the Single Market. Diverging national rules on R&D procurement, including pre-commercial procurement, constitute barriers that prevent companies from participating in and offering their services to public buyers in different Member States. Similarly, different approaches to the valuation and commercialisation of IP constitute barriers for innovators to attract IP-backed finance and scaleup their businesses across the Union. These fragmented approaches to R&D procurement and to the valuation and commercialisation of intellectual property impede cross-border movement of goods, services and capital within the Single Market.

2.2. Subsidiarity (for non-exclusive competence)

The proposed Regulation is in conformity with the principle of subsidiarity as provided for in Article 5(3) of the Treaty on the European Union.

Strengthening the Union's capacity to develop, commercialise, and scale innovative solutions is of high relevance for reinforcing the Union's competitiveness and strategic autonomy. Innovation ecosystems and markets for innovative companies are increasingly cross-border in nature, while regulatory and framework conditions in the Union are fragmented along national lines. In the absence of Union level measures, the competitiveness challenges currently facing industry are likely to prompt Member States to implement even more unilateral measures. While such efforts may be justified, leaving national measures uncoordinated and the cross-border challenges that are not tackled in national measures unaddressed risks negatively impacting the functioning and increasing the fragmentation of the Single Market, making the Union more vulnerable and overdependent on innovative solutions and technologies from third countries and unable to leverage the assets of the Single Market to deliver benefits to national and European ecosystems.

In particular, the scale required to support the transition from research to market and to ensure effective diffusion of innovation exceeds what individual Member States can achieve in isolation. Divergent national approaches to the valuation and commercialisation of intellectual property, to attract IP-backed finance, and to R&D procurement create legal uncertainty, increase costs and limit cross-border activities for innovative firms. These divergencies have a direct and demonstrable impact on the functioning of the Single Market, impeding cross-border movement of goods, services and capital within the Union.

By contrast, action at Union level can establish common framework conditions and ensure coordination across Member States, thereby enabling innovators to develop innovation, attract IP-backed financing and scale across the Single Market. Union-level action allows for the creation of a level playing field, reduces fragmentation and duplication, and facilitates efficient allocation of resources across the Union.

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No single Member State alone is capable of effectively addressing these issues due to the integrated nature of the challenge and the need for proper functioning of the Internal market for developing, testing, commercialising and scaling of innovative solutions across the Union. A harmonised Union-level approach is therefore necessary to ensure the well-functioning of the Single Market and to address the challenges of reinforcing the Union's competitiveness and strategic autonomy. The measures included in this initiative would not be as effective if implemented by Member States acting alone, as the challenges they address concern the Single Market. They are not limited to individual Member States or to a subset of Member States, but they relate to the Union's industrial base and Union-wide value chains. In addition, measures implemented at Member States' level are unlikely to adequately meet the needs of closely interconnected supply chains within the Single Market and could lead to further market fragmentation, innovation leakage and industrial relocation to other parts of the world and overall weakening of the Union's competitiveness and strategic autonomy.

Innovation is a trans-boundary challenge that requires Union-level action to effectively complement and reinforce measures taken at regional, national and local levels. The cost of inaction is pan-European. Without further Union action, the status quo is likely to persist, increasing the risk of the Union losing strategic industrial capacities and capabilities, of the Single Market to be further fragmented, and of the Union becoming critically dependent on third countries for green, digital, defence, and economic security objectives. This in turn could have negative implications on the Union's economic security, defence, social and territorial cohesion, primarily through impacts on employment, regional development, and equitable access to industrial opportunities.

The proposed measures therefore focus on areas where there is clear added value in acting at Union level due to the scale, speed and scope of the efforts needed. Actions aim at improving the business case for innovators to bring innovations to the market by facilitating the valuation, commercialisation and use of IP to obtain financing, and at making it easier to find first customers through R&D procurement, including pre-commercial procurement. It enhances efficiency by enabling better cross-border cooperation, ensures fairer access to opportunities for innovative companies irrespective of their location, and strengthens the Union's capacity to compete globally. The proposed measures also enable to improve the Union's competitiveness and strategic autonomy, while respecting the Union's international commitments towards its trade partners.

2.3. Proportionality

The proposed Regulation is proportionate to its objective of improving the functioning of the Single Market for innovation. Each of its components targets a specific objective and is limited to what is appropriate and necessary to achieve that objective, without going beyond what is required to address the identified barriers and without imposing disproportionate burdens on Member States and affected entities in Member States that are excessive compared to the benefits expected.

Firstly, common rules for R&D procurement, including pre-commercial procurement, will create significant time and cost savings for public buyers to conduct such procedures, enabling public buyers to modernise public services faster. and companies to accelerate business growth across the Single Market. A harmonised framework for joint cross-border R&D procurement enables public buyers to form the critical mass required to trigger industry to develop better value for money solutions and to enable companies to grow their business faster across the Single Market. The made in EU requirements for R&D procurement are proportionate to the European R&D capacities and designed as to not place significant

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financial burdens on administrative budgets. Establishing lead markets is pivotal to increasing EU competitiveness of across sectors and technologies, thereby strengthening the Union's industrial base and ensuring the Union's strategic autonomy. This combination of measures on R&D procurement is necessary to provide legal certainty, reinforce the Union's competitiveness and ensure effective implementation of the Treaty principles and the Union's international public procurement commitments. They are proportionate as they are limited to what is needed to achieve those objectives, designed not to place additional burden on Member States and public buyers, build on existing and widely used practices, and allow flexibility in their practical implementation.

Secondly, entrusting the European Union Intellectual Property Office with the establishment of a competence centre for IP-backed finance, as well as the development of a Union-wide IP valuation framework and a digital IP marketplace enables innovators, companies, universities and financial investors to lower valuation costs and increase the licensing and transfer of intellectual property rights in the Union. This is pivotal for increasing the commercialisation of research and innovation results across the Union. Building on the European Union Intellectual Property Office's existing mandate, expertise and resources ensures efficient implementation of these measures. Ensuring that the valuation framework is based on best practices for different types of IP rights and that the digital IP marketplace is designed to complement existing ones while offering the additional EU added value, ensures that these measures are proportionate, as they leverage existing structures, thereby reducing additional burden on Member States, and limit EU intervention to what is necessary to improve transparency, comparability and access in IP-related transactions.

2.4. Choice of the instrument

Article 114 of the Treaty on the Functioning of the European Union gives the legislator the possibility to adopt regulations and directives. For the present proposal, a regulation is considered the most appropriate instrument as it is immediately applicable and makes it possible to set requirements that apply directly to all the public and private actors targeted by the proposed measures. This will help ensure that the requirements are implemented in a timely and harmonised way, leading to greater legal certainty. It will ensure a consistent and coherent framework across the Union and to prevent divergences between national rules that hamper the development, testing and scale-up of innovation within the Single Market. A regulation is necessary to establish uniform framework conditions, reduce legal uncertainty and ensure a level playing field for innovators and innovative companies operating across borders. A directive would not be sufficient to reach the envisaged objectives, as it would require a time for transposition and may give rise to divergent transposition and implementation across Member States, thereby perpetuating fragmentation in the framework conditions for innovation.

A regulation is also a needed and appropriate legal instrument to amend Regulation (EU) 2017/1011 to enlarge the mandate of the European Union Intellectual Property Office and to ensure the effective application of the Union's exclusive competence in line with Article 207 of TFEU for those measures related to the access of economic operators from third countries to R&D procurement procedures.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

3.1. Stakeholder consultations

This proposal is based on extensive stakeholder consultations carried out in line with the Commission's Better Regulation principles and minimum standards. The Commission started

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consulting stakeholders on the barriers for innovation addressed by the European Innovation Act already in the context of the EU Startup and Scaleup Strategy. The Call for Evidence on the EU Startup and Scaleup Strategy was published on 17 February 2025 and closed on 17 March 2025. It gathered input from a broad range of stakeholders, including companies, business associations, research organisations, public authorities and individual respondents. The attracted 589 responses from stakeholders across 36 countries. The main barriers identified by stakeholders included difficulties for innovative companies to access procurements and underinvestment in innovation procurement in the EU, barriers to the commercialisation of research and innovation results and to the valuation of intellectual property, difficulties for innovative companies to access research and technology infrastructures, lack of experimentation possibilities in legislation across the EU and insufficient coordination between national and EU innovation policies and programmes. The EU Startup and Scaleup Strategy that was adopted on 28 May 2025 set out a comprehensive strategy to combine non-legislative as well as legislative measures to remove the identified barriers to innovation, the latter to be addressed through the European Innovation Act.

In preparation of this proposal, the Commission then carried out a dedicated Call for Evidence and Open Public Consultation to collect feedback on specific issues and to identify possible solutions for the legal barriers that were previously identified in the EU Startup and Scaleup Strategy. This Call for Evidence and Open Public Consultation were published on 8 July 2025 and closed on 3 October 2025. They gathered inputs from a broad range of stakeholders, including companies, business associations, research organisations, public authorities and individual respondents. In total, 336 responses were received to the Call for Evidence, including 193 position papers. The Open Public Consultation received 202 responses, complemented by 54 additional supporting documents.

Responses to the public consultation on the European Innovation Act were well distributed across stakeholder groups. Companies and businesses accounted for 27% of replies (55 responses), followed by business associations (23%, 47 responses) and academic and research institutions (16%, 33 responses). Other contributions were received from EU citizens (8%, 17 responses), non-governmental organisations (8%, 17 responses), public authorities (4%, 8 responses), trade unions (2%, 4 responses), non-EU citizens (1%, 3 responses), and other stakeholders (9%, 18 responses). Among participating companies, micro-enterprises (1-9 employees) represented the largest group (33%, 18 responses), followed by large companies (29%, 16 responses), small companies (20%, 11 responses) and medium-sized companies (18%, 10 responses).

The results of the Open Public Consultation and the corresponding synopsis report on the European Innovation Act were published on 4 December 2025 and are available online.[6]

In addition, a targeted consultation on the European Innovation Act was carried out between October and November 2025 to support the assessment of the expected costs and benefits of the proposed measures. This consultation combined 18 semi-structured interviews with selected stakeholders from the different sectors above, 55 responses to a targeted online survey, and three online focus groups held on 24, 26 and 27 November 2025. The focus groups were primarily aimed at validating the findings of the cost-benefit analysis.

Finally, a targeted consultation on the European Innovation Act was carried out with representatives responsible for research and innovation policies and programmes in Member

[6] Results of the Open Public Consultation and its Synopsis Report, 4 December 2025, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14593-European-Innovation-Act/public-consultation_en

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States and Horizon Europe associate countries that participate in the EIC Forum. The EIC Forum members adopted a joint Position paper and wish list for the European Innovation Act in November 2025.[7]

In total, 1210 responses were collected across these different rounds and types of consultations that helped prepare this proposal for the European Innovation Act. Overall, stakeholders expressed broad support for EU action to address the identified barriers to innovation. A large majority of respondents confirmed both the existence of the problems identified and the relevance of the measures proposed for the European Innovation Act that are aimed at improving the development, testing and scale-up of innovative solutions across the Single Market.

3.2. Collection and use of expertise

The preparation of this proposal draws on a broad evidence base, including analytical work, literature review, stakeholder input and expert advice.

The Commission carried out desk research and reviewed relevant academic literature, policy reports and data sources to support the analysis of the problems and policy options. This included, among others, data from Eurostat, the European Innovation Scoreboard, the Community Innovation Survey, the European benchmarking of national policy frameworks and investments in innovation procurement and the World Intellectual Property Organization (WIPO), as well as reports from international organisations such as the OECD and the European Patent Office (EPO), and peer-reviewed academic literature.

Inputs from the EIC Forum working groups and expert inputs were also used, including the report[8] of group of experts from 33 countries appointed by the Commission that formulated recommendations for the EU and EIC Forum member countries on how to overcome legal barriers that hamper wider implementation of innovation procurement, including R&D procurement, in the Union compared to other leading economies in the world.

An external contractor supported the Commission in carrying out additional desk research, analysing the results of the open public consultation and targeted consultations, organising focus groups and stakeholder interviews, and contributing to the cost-benefit assessment of the proposed measures.

The Commission's Joint Research Centre (JRC) provided further analytical support, including the analysis of the Call for Evidence and macroeconomic modelling to assess the potential impacts of the initiative.

3.3. Impact assessment

In line with the Better Regulation Guidelines, this regulatory proposal is supported by an impact assessment analysing the need to accelerate the commercialisation and uptake of innovative solutions and to create an innovation-friendly level playing field for innovative companies to scale up across the EU Single Market, in a context of growing global competitiveness challenges. The impact assessment identifies policy options to address the underlying problem drivers and assesses their likely impacts. It was developed in close

[7] Position paper and wishlist for the European Innovation Act, EIC Forum, November 2025, https://op.europa.eu/en/publication-detail/-/publication/b690e2af-d0bd-11f0-8da2-01aa75ed71a1/language-en

[8] Independent expert report, 'Overcoming legal barriers for the uptake of innovation procurement in the EU', May 2026, https://data.europa.eu/doi/10.2777/4586624

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consultation with the Commission's Inter-Service Steering Group on the European Innovation Act.

The draft impact assessment was submitted to the Regulatory Scrutiny Board ('the Board') on 23 December 2025. A meeting with the Board took place on 28 January 2026 and was followed by a negative opinion. Following a substantial revision to address the Board's comments, the impact assessment was resubmitted on 20 February 2026. In the second submission the Board acknowledged significant improvements, in particular regarding the reduced range of the proposed measures, the clarification of the context and scope of the initiative, and the overall presentation of the report. However, some substantive comments, in particular those related to the avoiding overlap with the upcoming revision of the EU Public Procurement Directives remained difficult to address, as the public consultation on the revision of these Directives had not completed yet and the planned measures and impact assessment of the revision of these Directives were not available yet at that time. The Board therefore maintained a negative opinion on 27 February 2026 and identified three main areas requiring further improvement in the Impact Assessment report for the European Innovation Act, namely to:

(1) **Ensure better coherence of the European Innovation Act's public procurement measures** with the upcoming revision of the EU Public Procurement Directives and further assess the proportionality and subsidiarity of the procurement measures, particularly regarding mandatory innovation procurement targets and the inclusion of public procurement below the financial thresholds established under the EU framework.

(2) **Ensure a more complete impact analysis** by extending the assessment of the European Innovation Act measures beyond the estimated population of innovative companies, as the proposed measures are not legally limited to a specific category of firms. Also requesting to address the absence of a legal definition of innovative companies within the European Innovation Act.

(3) **Provide a more in-depth assessment of the costs and benefits** of some European Innovation Act measures, with particular emphasis on:

- stronger estimation of the economic costs associated with mandatory innovation procurement targets and the introduction of an EU preference in public procurement;
- assessing the risk that too narrow definitions and principles for regulatory sandboxes could exclude potentially beneficial experimentation opportunities.

Following the Board's second negative opinion, the Impact Assessment was further substantially revised to address the identified shortcomings. The above-mentioned points were fully considered through a strengthened analysis and, where necessary, by adjusting the scope of the proposal. In particular, the comments of the Board were addressed in the following way:

- **The procurement measures on innovation-friendly procurement procedures and EU preference were narrowed down to focus exclusively on R&D procurement carried out by public buyers**. The innovation-friendly procurement techniques applicable to other forms of public procurement more broadly, were removed from the scope of the European Innovation Act. In addition, an EU financial threshold of EUR 216 000 (corresponding to the EU financial threshold used in the main public procurement Directive for sub-central authorities) was introduced, ensuring compliance with the principles of proportionality and subsidiarity.

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- **The mandatory target for Member States to increase overall innovation procurement spending was removed** from the scope of the European Innovation Act.
- **Explanation on definitions of innovative companies, startups and scaleups was added**. The Impact Assessment clarifies that, following the adoption of the EU Recommendation on definitions of innovative companies, innovative startups and innovative scaleups, the European Innovation Act no longer includes these definitions as part of the proposal. At the same time, it explains that, in line with the Better Regulation Guidelines, costs and benefits are estimated on the economically affected population (in particular innovative enterprises) rather than on all legally eligible entities. It clarified the difference between legally eligible and economically affected firms and explains more in depth how the number of affected entities was estimated.
- **Quantitative estimates were added.** The Impact Assessment provided additional cost and benefit analysis so that all measures included both Standard Cost Model and elasticity-based quantitative estimations of costs and benefits. In particular, it added the economic risk-related costs of procurement measures, refined the estimations for IP valuation and included dedicated sections explaining more in-depth the assumptions underlying each estimation.
- **The definitions and principles for regulatory sandboxes were removed** from the scope of the European Innovation Act and moved to a proposal for a Council Recommendation on regulatory sandboxes.

The Board's opinions as well as the final impact assessment and its executive summary are published together with this proposal.

The Commission carried out the impact assessment at the level of individual measures, with up to four variants considered for each measure as alternative policy options. This approach allowed for the identification of the most appropriate intervention for each specific problem area.

Finally, the preferred policy option for the European Innovation Act is defined as a composite package, combining the most effective variants of each of the nine measures assessed. For each measure, the selected variant is the one that performs best in terms of effectiveness, efficiency, coherence and proportionality. The preferred option therefore reflects a coherent combination of the strongest-performing elements across all measures, rather than a single predefined policy package.

The **preferred policy option** consists of the following measures.

First measure: the establishment, through the European Union Intellectual Property Office (EUIPO), of a competence centre for IP-backed finance, as well as the development of a Union-wide IP valuation framework and a digital marketplace. This measure is expected to increase IP transfer and licensing activity and the ability of innovators to attract IP-backed financing. It would entail administrative costs for EUIPO estimated at approximately EUR 712 000 and adjustment costs for EUIPO of around EUR 2.5 million, which will be covered by EUIPO's own resources, with no contribution from the Union budget. At the same time, this measure is expected to generate **administrative cost savings for companies of approximately EUR 35 million**. It is also estimated that the measure will generate **additional IP-backed venture capital and debit of EUR 10.2 billion every year for companies**.

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Second measure: the introduction of a harmonised procedure for R&D procurement and for joint cross-border R&D procurement. This measure is expected to generate **EUR 1 billion per year in cost saving for affected public buyers**, as well as **additional EUR 25.92 bn in firm profit every year**.

Third measure: the establishment of the EU preference for R&D procurement with opt-out clauses that allow procurement from non-covered suppliers where no suitable alternative from covered suppliers exists or where there are disproportionate cost differences between covered and non-covered suppliers[9]. This measure is expected to contribute to **strengthening the EU's open strategic autonomy**, in particular for critical technologies and strategic infrastructures, by reducing dependency risks and supporting the development of EU-based supply chains. The opt-out clauses are also estimated to **minimise the negative macro-economic effects of the EU preference**, estimated to be around EUR 464 million.

The combination of measures ensures coherence across the innovation lifecycle, addressing both supply- and demand-side barriers. By jointly improving framework conditions, access to resources and market opportunities, the preferred option maximises the effectiveness of individual measures and generates cumulative impacts beyond their standalone effects. Overall, macroeconomic simulation using the mentioned input costs and benefits estimate translated into an EU GDP increase of 0.25-0.42% over a ten-year horizon relative to a baseline scenario without the European Innovation Act, corresponding to up to 507,000 new jobs created across the EU over this ten-year horizon.

3.4. Regulatory fitness and simplification

The proposal is in line with the Commission's simplification objectives. By establishing more harmonised approaches across the Union for carrying out R&D procurement and tasking European Union Intellectual Property Office to establish a common framework for IP valuation, an EU wide marketplace for commercialising IP and a competence centre for IP-backed finance, it reduces duplication of costs, information asymmetries, and search and transaction costs for innovators.

Where new activities are introduced, the proposal builds on existing frameworks and processes, thereby limiting additional administrative burden.

For public authorities limited additional adjustment costs (EUR 45 million) are expected due to the need for increased training to implement R&D procurement techniques and EU preference. With the EU public sector expected to face adjustment cost (EUR 2.4 million) to develop the EU IP valuation framework, IP centre, and matchmaking platform. However, these additional administrative costs are offset by significant net administrative cost savings.

For firms and public buyers no additional administrative costs are expected as the proposed regulation does not impose additional obligations on them. On the contrary, additional administrative cost savings are expected for companies:

- EUR 1 billion per year for public buyers that aim to conduct R&D procurements, due to a harmonised framework for R&D procurement, including for joint cross-border R&D procurements;

[9] Covered suppliers are here suppliers from EU Member States and third countries that have concluded international agreements with the Union and in which the Union has commitments to open R&D services procurements to those third countries.

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- EUR 35 million per year for IP-rich firms, due to more harmonised approaches to IP valuation and easier IP licensing and transfer via the IP marketplace;

Overall, the preferred policy option is therefore expected to generate yearly net annual cost savings (administrative and adjustment costs combined) of approximately EUR 1.1 billion from the first year onwards, compared to the baseline, across both public and private stakeholders. Net savings are expected to increase further in subsequent years, as one-off adjustment costs are phased out and only recurring administrative costs remain.

4. FUNDAMENTAL RIGHTS

The proposed Regulation is based on a non-discriminatory approach and promotes transparency and equal treatment. It is not expected to significantly impact the fundamental rights protected under the Union Treaties and the Charter on Fundamental Rights.

5. BUDGETARY IMPLICATIONS

The estimated impact on expenditure and staffing for 2028 and beyond is added for illustrative purposes only and does not pre-judge the next Multiannual Financial Framework. The source of financing and scope of Union financial commitment in the post-2027 period remain subject to the outcome of interinstitutional negotiations on the MFF 2028-2034 and thereafter shall be determined through the annual budgetary procedure. All appropriations and staffing allocations as of 2028 are indicative. The proposal has budgetary implications for the Commission. Specifically, it will require approximately 3 full-time equivalents per year to implement. The budget implications are mainly to carry out the work foreseen to support and monitor the implementation of the Regulation, including to prepare delegated and implementing acts foreseen in the Regulation. The budget implications required for human resources and other expenditure of an administrative nature will be met by appropriations from the DG that are already assigned to management of the action and/or have been redeployed within the DG, together, if necessary, with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

6. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

Not Applicable

- **Detailed explanation of the specific provisions of the proposal**

The proposal consists of three Chapters. It is structured as follows:

Chapter I contains the general provisions setting out the subject matter and the scope of the proposed Regulation, as well as lays down the definitions applicable to the proposed Regulation. It clarifies that Chapter I of the Regulation only applies to R&D services procurements that fall outside of the scope of Directive (EU) 2014/23, Directive (EU) 2014/24 and Directive (EU) 2014/25 and it clarifies that Chapter III of the Regulation only applies to the European Union Intellectual Property Office.

Chapter II sets out common rules for implementing R&D procurement procedures, including joint R&D procurement.

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Chapter III sets out tasks entrusted by this Regulation to the European Union Intellectual Property Office to establish a common framework for intellectual property (IP) valuation, an EU wide marketplace for commercialising IP and a competence centre for helping innovators access IP-backed finance.

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2026/[…] (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

establishing a framework of measures for strengthening the Union innovation ecosystem and amending Regulation (EU) 2017/1001 (European Innovation Act)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[(1)],

Having regard to the opinion of the Committee of the Regions[(2)],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Important barriers remain, hindering access of innovations to the market and scaling of innovative enterprises in the Union. Innovators face lack of opportunities to bring innovative ideas to the Union-wide public procurement market due to the lack of a common legal framework for procurement of research and development services ('R&D procurement') and an underdeveloped internal market for intellectual property (IP) backed finance. National measures aimed at tackling such complex barriers that transcend national borders are fragmented and risk undermining the functioning of the internal market. This fragmentation creates obstacles to cross-border trade within the Union and distortions in the internal market. It is therefore necessary to establish harmonised measures to ensure the proper functioning of the internal market.

(2) While Directives 2014/23/EU[10], 2014/24/EU[11], and 2014/25/EU[12] harmonise procedures for public procurements falling within their scope, procedures for

(1) OJ C [...], [...], p. [...]

(2) OJ C [...], [...], p. [...]

10 Directive 2014/23/EU of the European Parliament and of the Council of 26 February 2014 on the award of concession contracts (OJ L 94, 28.3.2014, pp. 1, ELI: http://data.europa.eu/eli/dir/2014/23/oj).

11 Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.3.2014, pp. 65, ELI: http://data.europa.eu/eli/dir/2014/24/oj).

12 Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, pp. 243, ELI: http://data.europa.eu/eli/dir/2014/25/oj).

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procurements falling outside their scope are currently primarily governed by fragmented national rules or are exempt from national public procurement rules and are only subject to the fundamental principles under the Treaties as interpreted by the Court of Justice. This concerns the majority of R&D procurements, in particular those that fall outside the scope of those Directives because the benefits resulting from the R&D services procured do not accrue exclusively to the public buyer for its use in the conduct of its own affairs, as is the case in pre-commercial procurement, or because the R&D services procured are not wholly remunerated by the public buyer[13]. However, the application of those principles alone does not provide sufficient legal clarity to public buyers, address cross-border fragmentation in the implementation of R&D procurement or address structural barriers for public buyers to engage in joint cross-border R&D procurement. For that reason, for R&D procurements above a certain value, common rules should be adopted to ensure that those principles are given practical effect to ensure the proper functioning of the internal market.

(3) For R&D procurement procedures to which Article 25 of Directive 2014/23/EU, Article 14 of Directive 2014/24/EU and Article 32 of Directive 2014/25/EU do not apply, public buyers should be required to apply the provisions of this Regulation. However, the particular characteristics of defence procurement makes the procurement of R&D in that field especially sensitive, often requiring a high level of confidentiality and greater flexibility for Member States. Public buyers should therefore not be required to apply the provisions of this Regulation to R&D procurement falling under exemptions for R&D procurements laid down in Directive 2009/81/EC of the European Parliament and of the Council**Error! Bookmark not defined.**.

(4) To enhance access to business opportunities in R&D procurement and increase competition for the award of R&D procurement contracts, the participation of groups of economic operators should be further facilitated. This is of particular importance for SMEs, innovative startups and innovative scaleup, which often face difficulties in accessing larger R&D procurement opportunities. Therefore, the rules governing the participation of groups of economic operators and the use of combined capacities should be clarified and simplified, while ensuring that only requirements necessary for the proper performance of the R&D procurement contract are imposed.

(5) Subcontracting parts of an R&D procurement contract remains a practical and powerful tool of collaboration between economic operators. The rules for subcontracting in this Regulation should preserve contractual freedom and facilitate access for SMEs, innovative startups and innovative scaleup, enabling them to participate effectively in R&D procurement and related supply chains. Subcontracting the entirety of a R&D procurement contract should however not be allowed under this Regulation, in particular in order to avoid that subcontracting is misused especially in sectors which may be more vulnerable to labour exploitation owing to cost pressures and complex subcontracting chains.

(6) Without consulting the market, public buyers risk launching R&D procurement procedures on the basis of tender specifications that are insufficiently adapted to the actual capabilities of market operators, that favour established solutions, or that do not

[13] By virtue of Article 25 of Directive 2014/23/EU, Article 14 of Directive 2014/24/EU and Article 32 of Directive 2014/25/EU, those Directives only apply to R&D services procurements when the benefits accrue exclusively to the public buyer for its use in the conduct of its own affairs, and the service provided is wholly remunerated by the public buyer,

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provide sufficient scope for innovative solutions. Common rules should therefore be established to ensure that preliminary market consultations are conducted in a transparent and publicly accessible manner in preparation for such procedures.

(7) Negotiations, with the possibility for negotiation in stages, can enable public buyers to improve the quality, efficiency and overall value of the procured R&D services and their intended results, especially where the subject matter requires adaptation of procurement documents to operational and innovation needs or the balancing of other strategic considerations. Such optional flexibility should be provided to public buyers allowing them to decide to leave certain elements of the procurement documents open for negotiation, including the payment schedule or the dispute resolution mechanism, thereby lifting one of the major burdens for SME participation in public procurement.

(8) In accordance with the international and EU legal framework for public procurement, R&D procurement, including pre-commercial procurement, may include limited production and supply of prototypes or first products, services or works that are developed as part of the procured research and development services and public buyers may obtain ownership of this limited set of developed prototypes or first products, services or works, as they are part of the results of the R&D. To ensure transparency to economic operators, common rules shall ensure that public buyers specify in the procurement documents of an R&D procurement whether they will make use of the possibility to obtain the ownership of prototypes or first products, services or works that are developed as a part of the R&D procurement.

(9) For certain products, services or works that need to be procured after an R&D procurement for safeguarding security or public safety interests of the Union or its Member States, including to avoid shortages of supply for critical technologies, public buyers should be able to ensure that they will be able to purchase, via a separate procurement, the necessary amounts of products, services or works resulting from the R&D procurement. Therefore, common provisions should enable public buyers to include in the R&D procurement contracts provisions providing them with a priority right to purchase a predefined volume or value of such products, services or works, before these are offered to other potential buyers.I Including a priority right to purchase in R&D procurement contracts does not give public buyers the right to favour contractors that participated in the R&D procurement in later purchases of those products, services or works. Any such purchases need to be conducted in accordance with applicable EU public procurement rules.

(10) In line with the case law of the Court of Justice, the rights derived from Union public procurement law do not extend to economic operators having their origin in third countries with which the Union has not concluded trade agreements opening its public procurement market. To ensure the effective application of this case law and reinforce the Union's strategic autonomy, common provisions should be adopted that open the access to R&D procurements, generally, only to economic operators having their origin in third countries with which the Union has concluded trade agreements opening is R&D procurement market. Where this would result in a lack of tenders or disproportionate costs, public buyers should be allowed to open R&D procurement also to economic operators having their origin in third countries with which the Union has concluded trade agreements opening is public procurement market without commitments for opening its R&D procurement market. Where justified by security and public safety interests of the Union or its Member States, public buyers should be able to further restrict access to R&D procurements only to economic operators that

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have their origin in Member States and that are not subject to control of a third country.

(11) Clear and uniform rules on the determination of origin and control are necessary to ensure the effective and consistent application of international coverage and the access to R&D procurement provisions across all R&D procurement procedures. This Regulation should therefore establish rules of origin and control for the application of the rules on access to R&D procurement procedures set out herein.

(12) Economic operators should be excluded from participation in R&D procurement procedures where they have been convicted by final judgment for serious offences defined in Union legislation. Self-cleaning measures should not be permitted for mandatory exclusions, while for optional exclusions, which are related to the reliability of the economic operators, they should be able to demonstrate their reliability by means of self-cleaning measures. In that context, due account should be taken of any cooperation with the investigating authorities aimed at clarifying the relevant facts and circumstances. Member States should not add other grounds for exclusion based on criteria relating to professional situation of the tenderer but this does not prevent Member States from adding other legitimate grounds for exclusion, such as those aiming at preventing or addressing threats to national security.

(13) To ensure equal opportunities for all economic operators across the Union, common rules should ensure that public buyers do not use exclusion grounds, selection criteria and financial guarantee requirements in R&D procurement procedures that are disproportionate to the scope and nature of the R&D procurement contract. Where the use of mandatory exclusion grounds is required, the use of selection criteria and financial guarantee requirements remains optional and should not be used where not needed to ensure good outcomes for the R&D procurement. Public buyers should not require prior experience in R&D procurement contracts as such, unless this is strictly justified by the nature of the R&D services concerned, and should also avoid excessive administrative and financial requirements which can unnecessarily exclude innovative enterprises from R&D procurement opportunities. Innovative startups or scaleups that do not have a track record of turnover or financial statements but that are actually technically and financially viable as they possess other financial resources such as venture capital investments or valuable intellectual property assets should not be disqualified. Where financial guarantees are needed, they should be lowered for innovative startups, scaleups and SMEs, and public buyers should timely reduce or release financial guarantees once they are no longer justified.

(14) In R&D procurement, public buyers should apply award criteria and contract performance monitoring criteria based on the quality and innovation impact of the proposal rather than on price alone. Common rules should therefore be established on how such criteria should be formulated in order to take into account the added value of the proposal for the internal market. R&D procurement contracts should be awarded on the basis of the best price-quality ratio method. Ensuring that innovation contributes to improving the quality of public services and reinforcing strategic autonomy in R&D procurements, requires minimum safeguards against an excessive focus on price. This Regulation should therefore provide for a minimum weighting of 50% for quality criteria and a minimum weighting of 15% for innovation-related award criteria in the award phase.

(15) Excessively detailed requirements often contribute to unnecessarily reducing the participation of economic operators and can hamper innovation. To facilitate

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competitive R&D procurement markets, the characteristics of the R&D services and their intended results that are subject of the R&D procurement should, as a general rule be drafted by giving preference to functional requirements and where needed performance requirements instead of by designing prescriptive requirements. This could include specifying which functionalities the testing shall have at minimum, such as either, neither or both load testing and stress testing, , It could also include which performance the intended results of the testing shall have, for example what shall be the required accuracy level of the test data to be produced by the testing.

(16) Allowing contractors to retain the ownership of their IP, attracts more and better-quality offers to R&D procurements and saves public buyers IP registration, maintenance and litigation costs. It also enables contractors to commercialise their R&D results and sell developed products and services to the market through economies of scale. Public buyers should be able to maintain their freedom to operate and prevent supplier lock-in by obtaining appropriate rights to use the R&D results for themselves and for their other contractors. Where contractors fail to commercialise R&D results or abuse R&D results contrary to the public interest, public buyers should be able to resort to licensing or transfer of R&D results of contractors. Common rules should therefore be established to encourage that in R&D procurement the risks and benefits related to the results and the IP rights are shared between public buyers and contractors under market conditions. R&D procurements that are not pre-commercial procurements should be able to derogate from risk-benefit sharing under market conditions, in duly justified cases of overriding public interests.

(17) It is necessary to clarify certain aspects related to contract execution that have a close link with the procurement procedure itself, including payments, termination of contracts, and contract modifications. Timely payments, appropriate use of advance payments are important to minimise negatively affecting liquidity and complicating the financial management of economic operators. Obligations to terminate ongoing contracts should be defined to prevent infringements of Treaty obligations or exclusion grounds. In addition to continuing to allow public buyers to modify R&D procurement contracts for situations that were foreseen from the outset, it should be clarified how R&D procurement contracts can be modified in unforeseen conditions. The latter provisions should allow for better application in situations justifying a modification without launching a new R&D procurement procedure. The value of the modifications compared to the original R&D procurement contract should however be considered only as threshold for ex ante publication and potential review to combat potential misuse.

(18) It is necessary to provide legal certainty on how public buyers can correctly conduct value engineering in R&D procurement, as this generates significant cost savings and quality improvements for public buyers by allowing the flexibility to modify R&D procurement contracts in order to incorporate innovations emerging during the performance of the contract. Common rules should therefore be established to foster the use of value engineering in R&D procurement, particularly in large value R&D procurement contracts where the potential impact on cost or quality improvements is most significant.

(19) Multiple sourcing in R&D procurement facilitates market entry for new entrants and enables public buyers to reduce the costs of the R&D and its intended results by introducing competition in development (‘Competitive development’). It also helps public buyers to retain a competitive supply chain after the R&D procurement and reduce overdependencies on individual economic operators. Common rules for

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multiple sourcing in R&D procurement should be therefore established. R&D procurements that are not pre-commercial procurements should be able to derogate from using multiple sourcing, in duly justified cases of overriding public interests.

(20) Organising competitive development in phases also enables public buyers to reduce the number of contractors after each R&D phase, which reduces the R&D and investment risks for public buyers. A phased approach also enables contractors to grow their business along the growing tasks and contract sizes of successive R&D phases, which further eases market entry for smaller companies and new entrants. Common rules for competitive development in phases in R&D procurement should be therefore established. R&D procurements that are not pre-commercial procurements should be able to derogate from using competitive development in phases, in duly justified cases of overriding public interests.

(21) Insufficient protection of confidential information and personal data in R&D procurement can damage the contractor's business growth, the safety of public services and fundamental rights of third parties that participate in R&D activities. Therefor, neither public buyers nor contractors should disclose confidential information provided to them in the context of a R&D procurement. To ensure a consistent and high level of protection of natural persons, public buyers may also restrict the localisation of and access to the personal data that is processed in R&D procurements to the Union, in accordance with limitations on the transfer of personal data outside the Union set out in Regulation (EU) 2016/679[14] and Directive 2002/58/EC[15].

(22) Security and public safety considerations may arise in a wide range of R&D procurement procedures, including outside defence and sensitive security sectors. Common rules should be established for public buyers on assessing and addressing such risks in the design and conduct of R&D procurement procedures and in contract performance.

(23) The European Court of Auditors[16] has called on the Commission to address the low level of competition for public procurement in the Union. With the increasing digitalisation of the Union economy and the growing demand from public buyers across the Union for innovative solutions made in the Union, there is an increased cross-border interest from economic operators to participate in R&D procurement carried out by public buyers from other Member States and there is an increased interest from public buyers in different Member States to cooperate in organising their R&D procurement procedures. Common rules for joint procurement should therefore be established to overcome the hurdles that public buyers face today due to fragmented national rules to organise R&D procurement collaboratively, whether through central purchasing bodies or through joint procurement, including across borders.

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14 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119, 4.5.2016, pp. 1–88, https://eur-lex.europa.eu/eli/reg/2016/679/oj/eng.

15 Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) (OJ L 201, 31.7.2002, p. 37, ELI: http://data.europa.eu/eli/dir/2002/58/oj)..

16 Special Report 28/2023: Public procurement in the EU, European Court of Auditors, December 2023, https://www.eca.europa.eu/ECAPublications/SR-2023-28/SR-2023-28_EN.pdf

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(24) Economic operators face difficulties in leveraging IP assets to obtain growth financing due to the lack of consistent and reliable approaches to the valuation of intangible assets, of structured secondary markets for intangible assets and of skills on IP backed finance. A Competence Centre to support IP-backed finance and commercialisation of IP should therefore be established within the European Union Intellectual Property Office ('the Office') to develop a voluntary Union framework for the valuation and disclosure of IP rights, to set up and maintain a Union-wide, multi-lingual, digital match-making platform[17] that facilitates transparent and efficient IP transactions between investors and IP holders, and to support the financial community in designing and implementing financial instruments that are tailored to IP assets through advisory support, helpdesk services and skills development programmes. Access to the services provided by the Competence Centre should be voluntary.

(25) The Office should be able to levy charges for specific services provided through the Competence Centre for the individual benefit of users, in accordance with Article 178 of Regulation (EU) 2017/1001 of the European Parliament and of the Council[18]. Such charges should be transparent, non-discriminatory and limited to the cost of the service. Certain services, including access to the voluntary valuation framework, basic access to the digital match-making platform and the Union-level helpdesk, should remain free of charge.

(26) The effective use of the voluntary Union valuation framework requires assessments by qualified, independent and trustworthy professionals. The Office should therefore establish and administer a Union certification scheme for intellectual property valuators. The Commission shall, by means of implementing acts, lay down detailed conditions for the implementation of the certification scheme.

(27) The lack of accessible, consistent information across the Union on transactions in which IP rights are used as collateral hinders evidence-based policymaking and the development of new financial solutions. To that end, the Office should, through the Competence Centre, cooperate with Member States and relevant public and private stakeholders to collect and analyse Union-wide data on IP-collateralised transactions, while ensuring appropriate safeguards for trade secrets and personal data.

(28) The tasks conferred on the Office by this Regulation should be reflected in a separate section of its multiannual strategic programme and annual work programme, setting out the relevant objectives, activities, expected results, performance indicators and estimated resources. The annual activity report should contain a corresponding assessment of implementation, resources used and revenue from charges.

(29) Regulation (EU) 2017/1001 establishes the Office and lays down its tasks. That Regulation should therefore be amended to reflect the new tasks entrusted to the Office.

(30) In order to take account of technological development and maintain an efficient framework of measures for strengthening the innovation ecosystem at Union level, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of

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[17] IT development and procurement strategy choices will be subject to pre-approval by the European Commission Information Technology and Cybersecurity Board.

[18] Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark (OJ L 154, 16.6.2017, pp. 1, ELI: http://data.europa.eu/eli/reg/2017/1001/oj).

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the European Union should be delegated to the Commission in respect of: excluding tenders having their origin in a third-country that failed to provide national treatment related to Union economic operators in R&D procurement contrary to its commitments on public procurement in an international agreement with the Union; amending the list of cases in which public buyers can decide not to apply risk-benefit sharing, not to apply multiple sourcing or not to apply competitive development in phases; supplementing the rules in this Regulation with provisions on the cooperation mechanisms between Union entities and Member State entities when Union entities act as central purchasing bodies, facilitate or participate as public buyer in joint R&D procurements with Member State entities.

(31) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission for the adoption of technical specifications for the uniform application of the voluntary Union framework for the valuation and disclosure of IP rights; common technical standards, interoperability requirements and operational specifications of a digital match-making platform; and detailed conditions for the implementation of the certification scheme of intellectual property valuators. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council.

(32) Where the power to adopt acts in accordance with Article 290 of the Treaty is delegated to the Commission under this Regulation, it is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Inter-institutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council should receive all documents at the same time as Member States' experts, and their experts should systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(33) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures in accordance with the principle of proportionality, as set out in Article 5 of the Treaty on European Union. Furthermore, in accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

HAVE ADOPTED THIS REGULATION:

Chapter 1
GENERAL PROVISIONS

Article 1

Subject matter

This Regulation lays down common rules for carrying out procurement of research and development services ('R&D procurement') including a Union harmonised framework for joint R&D procurement.

This Regulation also establishes a Competence Centre at the European Union Intellectual Property Office and lays down the tasks of the European Union Intellectual Property Office in relation to intellectual property-backed finance and commercialisation of intellectual property.

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Article 2

Scope

1. Subject to paragraph 2, Chapter 2 of this Regulation applies to public procurement of research and development services with a value net of value added tax (VAT) estimated to be equal to or greater than EUR 216 000.

2. Chapter 2 of this Regulation does not apply to:

   (a) public procurement that falls within the scope of Directives 2014/23/EU, 2014/24/EU and 2014/25/EU;

   (b) public procurement that falls within the scope of Directive 2009/81/EC;

   (c) public procurement that is excluded from Directive 2009/81/EC by virtue of the provisions of that Directive.

3. Chapter 3 applies to the European Union Intellectual Property Office.

Article 3

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(1) '**procurement of research and development services ('R&D procurement')** means the procurement of fundamental research, industrial research and experimental development up to original development, where

   (1) original development of a first product, service or work may include limited production or supply in order to incorporate the results of field testing and to demonstrate that the product, service or work is suitable for production or supply in quantity to acceptable quality standards, but does not include quantity production or supply to establish commercial viability or to recover research and development costs.

   (2) procurement of research and development services may include obtaining the ownership of prototypes or first products, services or works that are developed at the public buyer's request in the course of and for a particular R&D procurement contract, not including the commercial deployment of end-products, services or works;

(2) '**pre-commercial procurement** means the procurement of research and development services that involves risk-benefit sharing under market conditions, and competitive development in phases.

(3) '**public buyer**' means a contracting authority as defined in Article 6(1) of Directive 2014/23/EU, in Article 2(1), point (1), of Directive 2014/24/EU, in Article 3(1) of Directive 2014/25/EU, or a contracting entity as defined in Article 7(1) of Directive 2014/23/EU and within the meaning of Article 4(1)of Directive (EU) 2014/25;

(4) '**R&D procurement contract**' means a contract concluded in writing between one or more economic operators and one or more public buyers and having as its subject-matter the provision of research and development services falling within the scope of this Regulation;

(5) **'tenderer'** means an economic operator that has submitted a tender;

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(6) **'contractor'** means an economic operator that has been awarded an R&D procurement contract;

(7) **'CPV codes for research and development services' means** the codes under Division 73 of the Common Procurement Vocabulary laid down by Regulation (EC) No 213/2008 of the European Parliament and of the Council[19].

(8) '**economic operator**' means any natural or legal person, or public entity or group of such persons and/or entities, including any temporary association of undertakings, which offers the execution of works and/or a work, the supply of products or the provision of services on the market;

(9) '**procurement document**' means any document produced or referred to by the public buyer to describe or determine elements of the procurement or the procedure, including the contract notice, the prior information notice where it is used as a means of calling for competition, the technical specifications, the descriptive document, proposed conditions of contract, formats for the presentation of documents by tenderers, information on generally applicable obligations and any additional documents;;

(10) '**multiple sourcing**' means an R&D procurement whereby one or more public buyers award multiple R&D procurement contracts in parallel to multiple economic operators and entrust them with the execution of identical or quasi-identical R&D services to be performed in parallel;

(11) **'minor informality or irregularity of a tender'** means an objectively identifiable defect in a tender that is purely formal in nature and does not concern an essential element of the tender, the correction or clarification of which does not result in a modification of the tender, does not amount to the submission of a new tender, and does not distort competition or infringe the principles of equal treatment and transparency;

(12) **'innovation**' means the implementation of a new or significantly improved product, service, work or process, marketing method, or organisational method in business practices, workplace organisation or external relations;

(13) '**SME**' means a micro, small or medium-sized enterprise as defined in the Annex to Commission Recommendation 2003/361/EC[20];

(14) '**innovative startup**' means an enterprise that fulfils the criteria of an innovative startup set out in point 3 of the Annex to Commission Recommendation (EU) 2026/720[21];

(15) **'innovative scaleup'** means an enterprise that fulfils the criteria of an innovative scaleup set out in point 4 of the Annex to Commission Recommendation (EU) 2026/720;

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[19] Regulation (EU) 213/2008 of the European Parliament and of the Council of 28 November 2007 amending Regulation (EC) No 2195/2002 of the European Parliament and of the Council on the Common Procurement Vocabulary (CPV) and Directives 2004/17/EC and 2004/18/EC of the European Parliament and of the Council on public procurement procedures, as regards the revision of the CPV (*O L L 74, 15/03/2008, pp. 1–375*, ELI: http://data.europa.eu/eli/reg/2008/213/oj).

[20] Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36, ELI: http://data.europa.eu/eli/reco/2003/361/oj).

[21] Commission Recommendation (EU) 2026/720 of 18 March 2026 on the definition of innovative enterprises, innovative startups and innovative scaleups, C/2026/1800

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(16) **'innovative enterprise'** means an enterprise that fulfils the criteria of an innovative enterprise set out in point 2.1 of the Annex to Commission Recommendation (EU) 2026/720;

(17) '**emergency situation**' means a sudden, unexpected, and severe disruption to economic operations, involving shortages of critical products, works or services, extreme price volatility, or supply chain breakdowns that necessitates immediate action to prevent further harm to the economy, businesses, or consumers in the Union;

(18) '**functional requirement**' means a requirement that describes the functions to be performed, without prescribing the specific technical means, design, solution or methods by which those functions are to be achieved;

(19) '**performance requirement**' means a requirement that defines the performance or outcomes to be achieved, including criteria for verifying compliance, without prescribing the specific technical means, design, solution or methods by which those outcomes are to be achieved;

(20) '**design requirement**' means a requirement that defines in detail technical characteristics that prescribe how the products, services or works that are developed at the public buyer's request in the course of and for a particular R&D procurement contract shall be designed, including materials, dimensions, and solutions, methods or processes that are to be used;

(21) **'results'** means any tangible or intangible outcomes of research, development and innovation activities, such as data, knowledge or knowhow, whatever its form or nature, whether or not it can be protected, as well as any rights attached to such outcomes, including intellectual property rights, that are generated, in whole or in part, through activities performed under the R&D procurement contract;

(22) **'value engineering'** means a technique used by public buyers to require or allow contractors to innovate during the performance of R&D procurement contract to create additional value for the public buyer that improves the performance, quality, cost or characteristics of the awarded research and development services and any prototypes, first products, services or works that are developed in the course of and for a particular R&D procurement contract, and to share any agreed resulting savings between the public buyer and the contractor;

(23) '**value engineering change proposal**' means a proposal submitted by contractors during the performance of the R&D procurement contract to improve the awarded research and development services and any prototypes, first goods, services or works that are developed in the course of and for a particular R&D procurement contract or to replace those research and development services or prototypes, first goods, services or works by others that incorporate technological advances or innovations, and which may involve replacing or adding a new consortium partner or subcontractor;

(24) '**value engineering clause**' means a contract clause in an R&D procurement contract that defines the rights and obligations of the buyer, contractors and subcontractors regarding how value engineering shall be applied under that contract;

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(25) **'critical technologies'** means the technologies in the critical technology areas listed in the Annex to Commission Recommendation (EU) 2023/2113[22];

(26) **'critical raw material'** means a raw material listed in Annex II to Regulation (EU) 2024/1252 of the European Parliament and of the Council[23];

(27) **'public and private entities in the fields of finance and insurance'** means public authorities, public sector bodies, public undertakings and other natural or legal persons active in the provision, financing, regulation, supervision or intermediation of financial services, within the meaning of Article 2(12) of Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights[24].

Chapter 2
PROCUREMENT OF RESEARCH AND DEVELOPMENT SERVICES

SECTION 1
R&D PROCUREMENT PROCEDURE AND CONTRACT PERFORMANCE

Article 4

General principles

1. Public buyers shall carry out R&D procurement in accordance with the rules laid down in this Regulation. Public buyers and economic operators shall not circumvent or attempt to circumvent the obligations laid down in this Regulation.

2. Public buyers shall treat economic operators equally and without discrimination and shall act in a transparent and proportionate manner. The R&D procurement shall not be designed with the intention of excluding it from the scope of this Regulation or of artificially narrowing competition. Competition shall be considered to be artificially narrowed where the design of the R&D procurement is made with the intention of unduly favouring or disadvantaging certain economic operators.

3. Public buyers may draw up the procurement documents and carry out R&D procurement, including the market consultation, tendering and contract performance activities, in any of the official languages of the Union and they may allow economic operators to submit market consultation feedback, tenders, deliverables and any other

[22] Commission Recommendation (EU) 2023/2113 of 3 October 2023 on critical technology areas for the EU's economic security for further risk assessment with Member States (OJ L, 2023/2113, 11.10.2023, ELI: http://data.europa.eu/eli/reco/2023/2113/oj)

[23] Regulation (EU) 2024/1252 of the European Parliament and of the Council of 11 April 2024 establishing a framework for ensuring a secure and sustainable supply of critical raw materials and amending Regulations (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1724 and (EU) 2019/1020 (OJ L, 2024/1252, 3.5.2024, ELI: http://data.europa.eu/eli/reg/2024/1252/oj)

[24] Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council (OJ L 304, 22.11.2011, p. 64, ELI: http://data.europa.eu/eli/dir/2011/83/oj)

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communication exchanges throughout the procurement in any of the official languages of the Union.

4. Public buyers shall by electronic means ensure that economic operators that have access to the procurement procedure have unrestricted and full direct access free of charge to the procurement documents, including documents prepared by public buyers for a market consultation, until three years after the award of the R&D procurement contract. Where for certain parts of these documents access by electronic means cannot be provided, public buyers shall indicate how these parts of the documents will be made available by other than electronic means.

5. In R&D procurement procedures requiring publication in the *Official Journal of the European Union*, public buyers shall use the applicable standard forms for notices laid down in Commission Implementing Regulation (EU) 2019/1780.

6. Public buyers shall take appropriate measures to ensure that, in the performance of R&D procurement contracts, economic operators comply with applicable obligations relating to the strategic priorities of the Union set out in the second subparagraph of this paragraph, as established by Union law, national law, or collective agreements and by the international environmental, social and labour law.

Public buyers shall design and execute their procurement in a manner that takes into account the strategic priorities of the Union, in particular:

(a) Boosting the Union's competitiveness through a thriving internal market, closing the innovation gap and reinforcing the Union's manufacturing and industrial base;

(b) the achievement of climate and environmental objectives of the Union;

(c) the pursuit of a fair and inclusive society;

(d) the Union's economic security, including through strategic independence.

Article 5

Economic operators

1. Economic operators that, under the law of the Member State in which they are established, are entitled to provide the relevant R&D services, shall not be rejected solely on the ground that, under the law of the Member State in which the contract is going to be awarded, the economic operator would have been required to be either a natural or legal person.

2. Public buyers may, in the case of R&D services, works or siting and installation operations, require legal persons to indicate before the start of the execution of the tasks concerned, the names and relevant qualifications of the staff responsible for the performance of the contract in question.

Article 6

Groups of economic operators

1. Groups of economic operators, including temporary associations without legal personality, may participate in procurement procedures. Public buyers shall not require economic operators including groups of thereof to have a specific legal form in order to participate in the procurement procedure.

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2. Public buyers shall not define selection criteria pursuant to Article 15 for groups of economic operators that differ from those for individual economic operators unless otherwise laid down in this Article.

Groups of economic operators shall be deemed to fulfil all relevant selection criteria, without needing to recourse to reliance on the capacity of other entities pursuant to Article 7, where:

(a) one economic operator in the group possesses the necessary technical and professional ability or economic and financial standing; or,

(b) where such ability or standing can be established by combining the relevant technical and professional ability or economic and financial standing from two or several members of the group, unless such combination will not achieve the same level of ability or standing.

3. When justified by the nature of the contract and in accordance with the principle of proportionality, public buyers may

(a) derogate from point (a) or (b) of the second sentence in paragraph 2 for selection criteria relevant for certain critical tasks;

(b) require that certain critical tasks be performed directly by the member of the group that fulfils the selection criterion relevant for that task.

Such requirements and justification shall be clearly indicated in the contract notice or in the procurement documents.

4. Conditions for the performance of the contract by groups may only differ from those imposed on individual economic operators, where justified by objective reasons, proportionate and clearly indicated in the procurement documents.

5. Without prejudice to Member States' competence to organize their social security systems, public buyers shall not require groups of economic operators to assume a specific legal form once they have been awarded the contract.

6. Public buyers shall give particular consideration not to create unjustified or disproportionate barriers related to the size of the economic operators participating in a group, in particular for SMEs, innovative startups and innovative scaleups.

Article 7

Reliance on the capacity of other entities

1. With regard to selection criteria as set out pursuant to Article 9, economic operators may rely on the capacities of other entities, regardless of the legal nature of the links which it has with them.

2. The public buyer shall verify whether the entities on whose capacity the economic operator intends to rely on fulfil the relevant selection criteria and whether there are grounds for their exclusion.

3. The public buyer shall require the economic operator to replace an entity which does not meet the relevant selection criteria, or in respect of which there are mandatory grounds for exclusion pursuant to Article 13. It may require the economic operator to replace an entity in respect of which there are voluntary grounds for exclusion pursuant to Article 14.

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4. Public buyers may request that the economic operator proves that it will have the relevant resources of the entity it intends to rely on at its disposal throughout the period of execution of the contract, for example by a statement to that effect by those entities.

5. Where an economic operator relies on the capacities of other entities with regard to criteria relating to economic and financial standing, the public buyer may require that the economic operator and those entities be jointly liable for the execution of the contract.

6. Where an economic operator relies on the capacities of other entities as proof of technical and professional ability, the public buyer may require that the entity the economic operator intends to rely on will perform the works or services for which these capacities are required.

Article 8

Subcontracting

1. A successful tenderer may subcontract parts of the contract. The contract awarded to the economic operator shall not be subcontracted in its entirety.

2. Public buyers shall require economic operators to indicate in their tender any share of the contract that they envisage to subcontract to third parties, and any proposed subcontractors.

   In the case of works contracts and in respect of services to be provided at a facility under the direct oversight of the public buyer, after the award of the contract and at the latest when the performance of the contract commences, public buyers shall require the main contractor to inform them of the tasks and activities its intends to externalise, as well as the identity of its subcontractors. The public buyer shall require the main contractor to notify the public buyer of any changes to this information during the course of the contract.

   Public buyers may require the information as referred to in the second subparagraph, or the information and identity of subcontractors of the main contractor's subcontractors, to other types of contracts.

3. The public buyer shall require the economic operator to replace a subcontractor in respect of which there are mandatory grounds for exclusion pursuant to Article 13. It may require the economic operator to replace a subcontractor in respect of which there are voluntary grounds for exclusion pursuant to Article 14.

4. When justified by the nature of the contract and in accordance with the principle of proportionality, public buyers may require that certain critical tasks be performed directly by the main contractor.

5. The provisions in this Article shall be without prejudice to the main contractor's liability.

6. Observance of the obligations referred to in Article 4(6) by subcontractors shall be ensured through appropriate action by the competent national authorities acting within the scope of their responsibility and remit.

Article 9

Market consultation

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1. Prior to launching the R&D procurement call for tenders referred to in Article 23, public buyers shall conduct a market consultation to inform economic operators of the forthcoming R&D procurement call for tenders and to gather their views on the proposed scope, value, and modalities of the implementation of the R&D procurement.

2. Public buyers shall announce the market consultation by means of a prior information notice. The notice shall:

   (a) be published in the *Official Journal of the European Union* and, after that, be published on the national public procurement portal of the Member State of the public buyer;

   (b) include references to the relevant CPV codes for research and development services, indicate that the market consultation is conducted for a R&D procurement and relates to innovation by marking the field 'innovation' in the prior information notice and by including, where applicable the words 'Pre-Commercial Procurement' in the field 'title of the procurement'.

   (c) include the estimated value of the R&D procurement calculated pursuant to the methodology laid down in Article 10(5)

   (d) include the format chosen by the public buyer for conducting the market consultation, such as online questionnaires, online webinars or physical meetings, and any relevant links or contacts where further information about the conduct of the R&D procurement can be obtained.

3. Public buyers shall consult the market widely. To this effect, after announcing the market consultation by means of a prior information notice, public buyers may publish and promote the announcement of the market consultations through any widely available media.

4. By way of derogation from paragraph 2 and 3, where necessary and justified for ensuring the protection of the security or public safety interests of the Union or one or several of its Member States withing the meaning of Article 28(2), public buyers shall publish and promote to the media the prior information notice omitting all sensitive information and requesting economic operators to express their interest to participate in the market consultation. Sensitive information shall be sent only to economic operators who have expressed interest, meet the qualification criteria and do not pose a security risk within the meaning of Article 28(4), point (d).

5. By way of derogation from paragraphs 2 and 3, where the publication and promotion in the media of a prior information notice and the publication of documents that explain the background and the logistical details for organising the market consultation would be contrary to the security or public safety interests of the Union or one or several of its Member States withing the meaning of Article 28(2), the public buyer shall not announce the market consultation pursuant to paragraph 2 and 3 but shall send an invitation to participate in the market consultation to potentially suitable economic operators identified through a market research and share the market consultation documents only with those who express interest, meet the qualification criteria and do not pose a security risk within the meaning of Article 28(4), point (d).

6. Public buyers shall not exclude any economic operators having their origin in countries referred to in Article 11(1), points (a) and (b), from participation in the market consultation. In derogation from the first sentence, where necessary and

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justified for protecting security and public safety interests of the Union or one or several of its Member States within the meaning of Article 28(2), public buyers may restrict market consultation only to economic operators that have their origin in Member States.

7. Public buyers shall ensure equal access to information during the market consultation. They shall share any information on the R&D procurement provided to one economic operator participating in the market consultation with all other economic operators participating in the same market consultation.

8. During the market consultation, public buyers may seek or accept information and advice from the general public, independent experts, public authorities, market participants or other relevant parties. Advice collected from market consultations may be used in the planning and conduct of the R&D procurement, provided that such advice does not distort competition and respects the principles of equal treatment, non-discrimination, fair competition and transparency.

9. Public buyers shall publish on their website the documents related to market consultation, including documents that explain the background and the logistical details for organising the market consultation, a report on the outcome of the market consultation, questions posed by economic operators together with the replies to those questions by the public buyer, written minutes of market consultation meetings and, where available, a video or audio recording of market consultation meetings. After the conclusion of the market consultation, public buyers shall update the prior information notice, published in accordance with paragraph 2, by including the link to that information.

10. The participation of an economic operator in a market consultation does not prejudge its eligibility to participate in a subsequent call for tenders for the R&D procurement.

11. By way of derogation from paragraph 1, the obligation to conduct a market consultation pursuant to this Article shall not apply to R&D procurement procedures which have as their only subject the procurement of research and development consultancy services as covered by CPV codes 73200000-4 to 73220000-0.

Article 10

Procurement documents

1. Public buyers shall specify in the procurement documents at least the following elements:

(a) the R&D procurement need in accordance with paragraph 4;

(b) the estimated value of the R&D procurement established in accordance with the methodology laid down in paragraph 5;

(c) the information on the conduct and the outcome of the market consultation made available in accordance with Article 9(7) and Article 9(9);

(d) the conditions for access to the R&D procurement, in accordance with the obligations laid down in Articles 11;

(e) the applicable exclusion grounds, selection criteria and financial guarantees in accordance with the obligations laid down in Articles 13 to 16;

(f) the minimum requirements to be met by all tenderers;

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(g) the innovation-related award criteria, including their respective weightings, to be applied in the evaluation of tenders, in accordance with the obligations laid down in Article 17;

(h) the division of the rights and obligations related to intellectual property rights and the ownership of results, in accordance with the obligations laid down in Article 19;

(i) the provisions for contract modifications and, where applicable, for value engineering, in accordance with the obligations laid down in Articles 20 to 21;

(j) the provisions for the call for tenders, including applicable provisions on negotiation laid down in paragraphs 2 to 3 of this Article and the minimum number of contractors that are to be selected where lots and multiple sourcing are used, in accordance with the provisions on the use for multiple sourcing laid down in Article 22 and with the provisions for the launch of the call for tenders laid down in Article 23;

(k) where applicable, the number of R&D phases over which the R&D activities are split and the intention of the public buyer to invite economic operators that have not participated in previous phases of the R&D procurement to participate in later phases of the R&D procurement, in accordance with the obligations for competitive development in phases laid down in Article 24;

~~(l)~~ whether and how the public buyer intends to obtain the ownership of results of the R&D procurement, including any prototypes or first products, services or works developed as a part of the R&D procurement;

(m) the innovation-related key performance indicators defined, to the maximum extent practicable as performance requirements, and the method for assessing them, to monitor the contract performance throughout the R&D procurement, in accordance with the obligations laid down in Article 24(5);

(n) the provisions for payments, in accordance with the obligations laid down in Article 25;

(o) the applicable confidentiality and data protection obligations, in accordance with the obligations laid down in Article 26;

(p) where applicable, any requirements for contractors to contribute to standardisation, certification or publication of results, including by making them available as open data or open source, without prejudice to confidentiality and data protection obligations referred to in Article 26 and to the obligations in respect of the protection of intellectual property rights laid down in Article 19;

(q) the provisions on the termination of R&D procurement contracts, in accordance with the obligations laid down in Article 27 and Article 29;

(r) the applicable security and public safety obligations, in accordance with the obligations laid down in Article 28 to Article 30;

(s) where applicable, the provisions for conducting the procedure as a joint R&D procurement, in accordance with the obligations laid down in Article 31.

(t) that the provisions of this Regulation apply to the R&D procurement.

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2. Public buyers shall indicate in the procurement documents that the essential conditions of the contract are not subject to negotiation. Public buyers shall not substantially alter the subject matter of the R&D procurement contract as a result of the negotiations. Negotiations may concern all characteristics of the research and development activities and of the intended results to be developed for the public buyer during those research and development activities as part of the R&D procurement, including quality, quantities as well as social, environmental and innovative aspects, may be subject to negotiation, provided that those characteristics do not constitute minimum requirements.

3. Public buyers shall, in the procurement documents, indicate any specific elements not listed in paragraph 1 for which they invite tenderers to indicate, in their tender, their preferred approach, leaving the finalisation of those elements subject to negotiation.

4. Public buyers shall draft the procurement documents for the R&D procurement taking into account the findings of the market consultation and any market research that the public buyer conducted on the state of the art of any ongoing research and development and product planning roadmaps of economic operators. Public buyers shall formulate the R&D procurement need referred to in point (a) of paragraph 1 as a problem that needs to be solved without unduly restricting possible approaches to solve the problem. Public buyers shall give preference to use functional requirements or performance requirements in accordance with Article 18 to formulate the requirements for addressing the R&D procurement need. The information provided in the procurement documents shall be sufficiently precise to enable economic operators to identify the nature and scope of the R&D procurement and to decide whether to submit a tender.

5. Public buyers shall calculate the estimated value based on the maximum estimated value net of VAT of the research and development services to be provided in the context of the R&D procurement contract or contracts, that are expected to be awarded as part of the R&D procurement procedure, including any lots, options or renewals. The calculation of the estimated value shall take into account the estimated value of all types of research and development related expenses, irrespective of their share in the total estimated value, including the value of labour, materials, components and tools that are needed to deliver the expected results, including, where relevant, research and development that was performed before the start of the R&D procurement procedure. Where public buyers intend to obtain the exclusive ownership of intellectual property rights to results generated by contractors, the estimated value shall include the estimated value of those intellectual property rights.

6. As regards products, services or works that result from the research and development services procured and that are needed to safeguard security and public safety interests of the Union or one or several of its Member States within the meaning of Article 28(2), including to avoid security of supply issues, public buyers may, in the procurement documents, specify that public buyers have a priority right to purchase a predefined volume or value of those products, services or works before these are offered to other potential buyers. In such case, public buyers shall set out the priority right to purchase as a contractual obligation in the R&D procurement contract.

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Article 11

Conditions for access to R&D procurement procedures and place of performance conditions

1. Public buyers shall open the participation in R&D procurement only to:

   (a) economic operators having their origin in Member States;

   (b) economic operators having their origin in countries that have concluded an international agreement with the Union, provided that R&D procurement falls within the scope of the Union's public procurement commitments in that agreement.

2. The Commission is empowered to adopt delegated acts in accordance with Article 39 to exclude, in whole or in part, subject to the Union's international obligations, a third country from the scope of paragraph 1, first subparagraph, point (b) based on any of the following criteria:

   (a) that third country has failed to provide national treatment related to Union R&D services or entities under the agreements referred to in paragraph 1, first subparagraph, point (b);

   (b) such exclusion is justified to avoid dependencies or any other developments that may threaten the security of supply in the Union of the relevant products, works or services in question;

   (c) such restriction is justified under any other exception under the applicable agreement.

3. By way of derogation from the second subparagraph in paragraph 1, where necessary and justified for ensuring the protection of the security interests of the Union or one or several of its Member States within the meaning of article 28(2), public buyers may restrict participation in R&D procurement only to economic operators that have their origin in Member States and that are not subject to control of a third country or of a legal entity that is subject to control of a third country.

4. By way of derogation from paragraph 1 point (b), public buyers may open the access to the R&D procurement also only to economic operators that have their origin in countries that have concluded an international agreement with the Union in which the Union has made public procurement commitments but not for R&D procurements, only in one of the following cases:

   (a) where no suitable tenders or requests to participate have been submitted, including in response to a similar R&D procurement procedure launched by the same public buyer in the two years preceding the launch of the planned new R&D procurement procedure; or

   (b) where limiting the access to the R&D procurement procedures in accordance with paragraph 1 would oblige the public buyer to procure at disproportionate costs.

For the purposes of the first subparagraph, point (b), an estimated difference of more than 20 % between the estimated cost of an offer from an economic operator having their origin in a country in paragraph 1, first subparagraph, points (a) and (b) and that from an economic operator having their origin in a country other than one of the countries referred to in paragraph 1, first subparagraph, points (a) and (b) on the basis of on objective and transparent data, may be presumed by public buyers to be disproportionate.

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5. Subcontracting may not be used with the intent or effect to circumvent the rules on access to R&D procurement. The rules on access to R&D procurement do not apply to entities on whose capacity the tenderer relies or to subcontractors, unless public buyers limit subcontracting:

   (a) where paragraph 1 or 4 applies, to subcontractors that have their origin in the countries listed in paragraph 1, points (a) and (b); or

   (b) where paragraph 3 applies and where necessary and justified for ensuring the protection of the security and public safety interests of the Union or one or several of its Member State within the meaning of Article 28(2), to subcontractors that have their origin in Member States and that are not subject to control of a third country or of a legal entity that is subject to control of a third country.

6. Where paragraph 4 applies, public buyers may reserve a number of R&D procurement contracts within the same R&D procurement procedure:

   (a) for economic operators that have their origin in the countries referred to in paragraph 1, first subparagraph points (a) and (b); or

   (b) where necessary and justified for protecting the security or public safety interests of the Union or one or several of its Member States within the meaning of article 28(2), for economic operators that have their origin in Member States and that are not subject to control of a third country or of a legal entity that is subject to control of a third country.

7. Public buyers shall require that contractors perform at least 50% of the research and development activities under the R&D procurement contract in the countries referred to in paragraph 1, points (a) and (b), including the work of principal research and development staff with scientific responsibility for the R&D procurement contract.

8. Where necessary and justified for protecting the security or public safety interests of the Union or one or several of its Member States within the meaning of Article 28(2), public buyers may require, in addition to the measure in paragraph 7, contractors to perform all research and development activities relating to new security components of the intended results in the Union, including the work of principal research and development staff with scientific responsibility for the R&D procurement contract.

9. Where an economic operator fails to provide information or documentation requested by the public buyer related to the verification of the place of performance conditions referred in paragraphs 7 and 8 without any reasonable explanation and thereby prevents the verification of the economic operator's compliance with the place of performance conditions by public buyers or makes such a verification practically impossible or very difficult, that economic operator shall be excluded from participation in the R&D procurement procedure.

10. As regards R&D procurement that benefit from Union funding, public buyers shall apply the provisions on the participation of economic operators laid down in this Article without prejudice to participation requirements set out in the legal acts governing those Union funding.

11. Public buyers shall determine the countries referred to in paragraph 1, first subparagraph, point (b), and paragraph 4 also on the basis of the online tool that the Commission shall establish and make available free of charge for this purpose.

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Article 12

Determination of origin and control

1. The origin of an economic operator shall be deemed to be:

(a) in the case of a natural person, the country of which the person is a national or where that person has a right of permanent residence;

(b) in the case of a legal person, either of the following:

(i) the country under the laws of which the legal person is constituted or otherwise organised and in the territory of which the legal person is engaged in substantive business operations;

(ii) if the legal person is not engaged in substantive business operations in the territory of the country in which it is constituted or otherwise organised, the origin of the legal person is to be that of the person or persons who controls the legal person by virtue of their ownership of that legal person, their financial participation therein, or the rules which govern that legal person.

2. Control shall be presumed to be the ability to exercise dominant influence directly or indirectly on a legal person in any of the following cases:

(a) by holding the majority of the legal person's subscribed capital;

(b) by controlling the majority of the votes attaching to shares issued by the legal person; or

(c) by being able to appoint more than half of the legal person's administrative, management or supervisory body.

3. Public buyers may, at any time during a R&D procurement procedure, request the economic operator to submit, supplement, clarify or complete the information or documentation related to the verification of the economic operator's origin and control within an appropriate time limit, provided that such requests are made in compliance with the principles of equal treatment and transparency. Where the economic operator fails to provide such information or documentation without any reasonable explanation and thereby prevents the verification of the economic operator's origin and control by public buyers or makes such a verification practically impossible or very difficult, that economic operator shall be excluded from participation in the R&D procurement procedure concerned.

Article 13

Mandatory exclusion grounds

1. Public buyers shall at any time exclude an economic operator from participation in a R&D procurement procedure where that economic operator, or key persons in its functioning in case of legal persons, has been the subject, in any Member State, of a conviction by final judgment, for or, regarding Member States not bound by the relevant Union act, as defined in equivalent national legislation:

(c) participation in a criminal organisation, as defined in Article 2 of Council Framework Decision 2008/841/JHA;

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(d) corruption offences, as defined in as defined in Directive 2026/1021/EU;

(e) fraud within the meaning of Article 1 of the Convention on the protection of the European Communities' financial interests[3] and offences referred to in Article 3 to 5 under Directive (EU) 2017/137;

(f) terrorist offences and offences related to a terrorist group, as well as offences related to terrorist activities, as defined in Articles 3 to 12 of Directive (EU) 2017/541;

(g) Money laundering, as defined in Article 3 of Directive 2018/1673/EU;

(h) trafficking in human beings as defined in Article 2 of Directive 2011/36/EU as amended by Directive 2024/1712 of the European Parliament and of the Council;

(i) criminal offences concerning the employment of illegally staying third-country nationals, as defined and sanctioned in Articles 3 and 9 of Directive 2009/52/EC;

(j) environmental criminal offences referred to in Articles 3 and 4 of Directive (EU) 2024/1203;

(k) criminal offences concerning the violation of Union Restrictive Measures as referred to in Article 3 and 4 of Directive (EU) 2024/1226;

(l) fraudulent use of non-cash payment instruments as referred to in Articles 3 to 8 of Directive 2019/713/EU;

(m) offences as referred to in Article 3 to 9 of Directive 2011/93/EU on combating the sexual abuse and sexual exploitation of children and child sexual abuse material;

(n) infringements of rules on the making available and the export of certain commodities and products associated with deforestation and forest degradation laid down in Regulation 2023/1115/EU.

Key persons in the functioning of a legal person means a member of the administrative, management or supervisory body of that economic operator or having powers of representation, decision or control therein.

The exclusion grounds set out in this article shall apply during five years from the date of the delivery of the final judgment, except where the period of exclusion has been set by the final judgment.

2. Public buyers shall at any time exclude an economic operator from participation in a R&D procurement procedure where, at the time when the public buyer takes the decision to exclude the economic operator, the economic operator or contractor is in breach of its obligations relating to the payment of taxes or social security contributions, except if by that moment in time, it has concluded a binding arrangement on paying the taxes or social security contributions due, including, where applicable, any interest accrued or fines.

[3] Council Act of 26 July 1995 drawing up the Convention on the protection of the European Communities' financial interests, OJ C 316, 27.11.1995, pp. 48–57,

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Public buyers may derogate from the mandatory exclusion provided for in subparagraph 1 where an exclusion would be clearly disproportionate, in particular where only minor amounts are unpaid.

3. Public buyers may decide to derogate from the mandatory exclusion provided for in paragraphs 1 and 2, on an exceptional basis, where such derogation is provided for in national law, for overriding reasons relating to the public interest such as public health or protection of the environment.

Article 14

Optional exclusion grounds

1. Public buyers may at any time exclude an economic operator from participation in a R&D procurement procedure, where:

   (o) the public buyer can demonstrate by any appropriate means that the economic operator has breached applicable obligations under relevant Union legislation, as referred to in Article 4(6);

   (p) where the economic operator is bankrupt or is the subject of insolvency or winding-up proceedings or a comparable situation;

   (q) where the public buyer can demonstrate by appropriate means that the economic operator is guilty of grave professional misconduct, which renders its integrity questionable;

   (r) where the public buyer has sufficiently plausible indications to conclude that the economic operator has entered into agreements with other economic operators aimed at distorting competition;

   (s) where the economic operator has shown significant or persistent deficiencies in the performance of a substantive requirement under a prior public contract, which led to early termination of that prior contract, damages or other comparable sanctions by the public buyer;

   (t) where the economic operator has been guilty of serious misrepresentation with regard to the information required for the verification of the absence of grounds for exclusion or the fulfilment of the selection criteria; or has otherwise undertaken to unduly obtain advantages in the public procurement procedure;

   (u) where the public buyer can demonstrate by any appropriate means, including protected data sources or assessments provided by competent national authorities, that the economic operator does not possess the reliability necessary to exclude risks to the security and public safety interests of the Union or of one or several Member States.

2. Any economic operator that is in one of the situations referred to in paragraph1 may provide evidence to the effect that it has taken sufficient measures to demonstrate its reliability despite the existence of a relevant ground for exclusion.

   For this purpose, the economic operator shall, in particular, prove that it has

   (v) paid or undertaken to pay compensation in respect of any damage caused by the misconduct;

   (w) clarified the facts and circumstances in a comprehensive manner by actively cooperating with the investigating authorities; and

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(x) taken concrete technical, organisational and personnel measures that are appropriate to prevent further misconduct.

If the public buyer considers the evidence provided as sufficient, the economic operator concerned shall not be excluded from the R&D procurement procedure.

The measures taken by the economic operators shall be evaluated taking into account the gravity and particular circumstances of the misconduct. In assessing the measures taken by the economic operator public buyers shall take into account the nature, extent and timing of the cooperation with the relevant investigating authorities.

Where the measures are considered to be insufficient, the economic operator shall receive a statement of the reasons for that decision.

An economic operator which has been excluded by final judgment in any Member State from participating in R&D procurement procedures shall not be entitled to make use of the possibility provided for under this paragraph during the period of exclusion resulting from that judgment.

3. The maximum period within which an economic operator may be excluded, if no measures as specified in paragraph 2 are taken and where the period of exclusion has not been set by final judgment, shall not exceed five years from the date when the relevant event has occurred.

Article 15

Selection criteria

1. Where public buyers decide to make use of selection criteria as requirements for participation in R&D procurement procedures, they shall design such criteria in accordance with the conditions in this Article.

2. Selection criteria for R&D procurement procedures shall only relate to:

(a) suitability to pursue the professional activity within the meaning of paragraph 4;

(b) technical and professional ability within the meaning of paragraph 5;

(c) economic and financial standing within the meaning of paragraphs 6 to 8.

3. Public buyers shall limit any requirements for selection criteria to those that are appropriate to ensure that an economic operator has the required capacities and abilities to perform the R&D procurement contract. All requirements for selection criteria shall be proportionate, linked to the subject-matter of the R&D procurement contract and comply with the principles of transparency, non-discrimination and proportionality.

Each reference to be provided as means of proof of compliance with any of the selection criteria shall be accompanied by the words ‘or equivalent’ to allow tenderers to provide any type of alternative evidence of compliance.

4. Public buyers may require economic operators to be enrolled in one of the professional or trade registers established in the country where the economic operator conducts its main activity. In R&D procurement procedures, in so far as economic operators are required to hold a particular authorisation or to be members of a particular organisation in order to be able to perform the research and development activities concerned in the country where the economic operator conducts its main

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activity, the public buyer may require such economic operators to provide proof that they hold such authorisation or membership.

Certified registration on official lists held by the competent bodies or a certificate issued by the certification body shall constitute a presumption of compliance with regard to the requirements laid down in the first and second subparagraphs.

5. Public buyers may impose requirements ensuring that economic operators possess the necessary human and technical resources and experience to perform the R&D procurement contract to an appropriate quality standard.

Unless justified by the complexity of the R&D procurement contract, public buyers shall not require prior experience in other contracts as a condition for participation in an R&D procurement procedure. A public buyer may assume that an economic operator does not possess the required professional abilities in either of the following cases:

(a) where the public buyer has established by any means that the economic operator has conflicting interests in relation to the subject matter of the R&D procurement contract which may negatively affect the performance of the that contract;

(b) where the public buyer has been made aware by any means that the economic operator presents a security risk within the meaning of Article 28(4), point (d).

Public buyers shall not require prior experience in other contracts without requiring that contractors possess the necessary human and technical resources to perform the R&D procurement contract. Public buyers shall not deem economic operators non-compliant with the requirements on technical and professional ability solely due to lack of prior experience in other contracts.

6. Where public buyers require economic operators to have minimum economic and financial standing, they may require economic operators to have one or both of the following:

(a) a certain minimum financial capacity;

(b) an appropriate level of professional risk indemnity insurance.

7. Where public buyers require economic operators to provide proof of minimum economic and financial standing, public buyers shall allow economic operators to provide such proof by any appropriate means, including any of the following:

(a) statements from banks or, where appropriate, evidence of relevant professional risk indemnity insurance;

(b) financial statements or extracts from financial statements, where publication of financial statements is required under the law of the country in which the economic operator is established;

(c) a statement of the economic operator's turnover for a maximum of the last three financial years available, depending on the date on which the economic operator was set up or started trading, as far as the information on such turnovers is available;

(d) a business plan supported by statements or other evidence of the economic operator's tangible and intangible financial assets, including its intellectual

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property assets, financial contributions from financial investors or funding bodies, or evidence of own capital invested in the economic operator.

Where a minimum financial capacity is required, it shall not exceed the estimated value of the R&D procurement contract, except in duly justified cases such as relating to the special risks attached to the nature of the procured research and development services. R&D procurement contract. The public buyer shall specify the main reasons for such a requirement in the procurement documents.

In assessing the minimum financial and economic standing, public buyers may consider information from the annual accounts of the economic operator only where the public buyer has specified the methods and criteria for such consideration in the procurement documents. Such methods and criteria shall be transparent, objective and non-discriminatory.

Where public buyers impose economic and financial standing selection criteria in accordance with paragraph 6, public buyers shall enable tenderers to provide the proof referred to in paragraph 7, point (d), between the date that the public buyer notifies tenderers about the decision to award the R&D procurement contract and the date of signature of that contract.

8. Where public buyers require professional risk indemnity insurance, they shall ensure and shall provide justification in the procurement documents that the required liability coverage is proportionate to the reasonably foreseeable amount of loss or damage that contractors and subcontractors may cause during or as a result of the performance of the R&D procurement contract.

9. Where the R&D procurement procedure applied by the public buyer does not include a preselection of economic operators on the basis of exclusion grounds or selection criteria, the public buyer shall request full documentary evidence proving compliance with applicable exclusion grounds and selection criteria only from the winning tenders that ranked highest based on the award criteria. Public buyers shall ensure that the verification of absence of grounds for exclusion and of fulfilment of the selection criteria is carried out in an impartial and transparent manner so that no contract is awarded to a tenderer that should have been excluded pursuant to Article 13 or Article 14, or that does not meet the selection criteria set out by the public buyer. Information that can be determined from existing national databases established by a public body, or from the registration on official lists or certifications shall not be questioned without sufficient justification.

10. Where information or documentation submitted by economic operators is or appears to be incomplete or erroneous or where specific documents are missing, public buyers, in compliance with the principles of equal treatment and transparency, shall provide the economic operators concerned with the opportunity to submit, supplement, clarify or complete the relevant information or documentation within an appropriate time limit to remedy any deficiency resulting from a minor informality or irregularity of a tender that does not put into question the decision to award R&D procurement contracts.

Article 10

Financial guarantees

1. Public buyers may require tenderers to provide tender guarantees, performance guarantees or retention guarantees provided that all of the following conditions are met:

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(a) the amount of the tender guarantees does not exceed 2% of the total estimated R&D procurement contract value, with a maximum amount of the tender guarantee of EUR 500 000 for R&D procurement contracts with an estimated value above EUR 5 000 000 and EUR 100 000 for contracts with an estimated value below EUR 5 000 000.

(b) for R&D procurement contracts with an estimated contract value above EUR 500000, the amount of the performance and retention guarantees does not exceed 5% of the specific contract price, which may be increased to 10% for highly complex or risky R&D procurement contracts when justified by a risk analysis. For R&D procurement contracts with an estimated contract value below EUR 500000, no performance or retention guarantees shall be required.

2. The values of tender, performance and retention guarantees that public buyers require from tenderers shall be reduced by 50% for SMEs, innovative startups and innovative scaleups.

3. Public buyers shall ensure the timely reduction or release of financial guarantees once they are no longer justified.

Article 17

Innovation-related award criteria

1. In R&D procurement procedures, public buyers shall apply quality award criteria designed to measure the potential impact of the received tenders on innovation and on creating added value for the Union. Such innovation-related award criteria shall include the following:

(a) the degree of innovativeness of the tender and the extent to which this degree of innovativeness contributes to the overall quality of the proposal that is to be researched, developed or tested during the R&D procurement, where possible by using quality criteria that are specific to the intended results of the R&D procurement;

(b) the total cost of ownership and long-term benefits of the tender, including the impact of any value engineering approach that is proposed in the tender on those costs and benefits;

(c) the impact of the tender on reinforcing the technology supply chain and developing an innovation ecosystem in the Union, including for critical technologies;

(d) the share of the value of the activities that are proposed to be carried out in the Union as a part of the R&D procurement contract;

(e) where applicable, the extent to which the tender proposes to integrate technologies developed in the Union, including research and development results stemming from publicly funded research and development programmes in the internal market and makes use of tools, such as standards, specifications, software or models or other technology developed in the Union.

2. Public buyers may apply other award criteria in addition to those laid down in the first paragraph. The combined weight of all innovation-related award criteria shall be at least 15% of the total weight of all award criteria, and the combined weight of the award criteria referred to in paragraph 1, points (c) to (e) shall not exceed 15% of the

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total weight of all award criteria. The combined weight of all quality award criteria shall represent at least 50% of the total weighting of all award criteria.

3. Public buyers shall evaluate the tenders received according to the best price-quality ratio method. To determine the best price-quality ratio, public buyers shall evaluate the tenders through a comparison of their price, costs and quality, the latter based on quality criteria linked to the subject matter of the R&D procurement contract.

4. By way of derogation from paragraph 1 and 2, the obligation to apply innovation-related award criteria pursuant to this Article shall not apply to R&D procurement procedures which have as their only subject the procurement of research and development consultancy services as covered by CPV codes 73200000-4 to 73220000-0.

Article 18

Formulating requirements for the characteristics of the procured R&D services

1. Public buyers shall formulate the requirements for the characteristics of the procured research and development services and of their intended results in the procurement documents in the following order of precedence:

   (a) requirements mandated by law;

   (b) functional requirements;

   (c) performance requirements;

   (d) design requirements;

   Public buyers shall apply the order of preference set out in the first subparagraph to each characteristic individually.

   Unless otherwise provided in applicable Union or national law, public buyers shall draft all requirements referred to in this paragraph in a manner that allows the tenderer to prove compliance by means of any alternative equivalent evidence.

2. Public buyers shall only formulate a requirement as a performance requirement, or design requirement, where it is impracticable to draft such requirement as a functional requirement.

3. Where for a specific characteristic there is no requirement mandated by law and where a specific characteristic cannot be sufficiently described through the requirements in paragraph 1, the requirements for that characteristic may be formulated in any of the following ways by reference, in order of preference, to:

   (a) harmonised standards cited in the Official Journal of the EU;

   (b) national standards transposing European standards;

   (c) European Assessments Documents;

   (d) common technical specifications;

   (e) international standards;

   (f) other technical reference systems established by the European standardisation bodies;

   (g) when any of the above does not exist: national standards, national technical approvals or national technical specifications.

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Each reference shall be accompanied by the words ‘or equivalent’ unless the reference is made to mandatory harmonised technical specifications.

4. Public buyers shall ensure that the procurement documents do not refer to a specific make, brand name or source, or a particular process which characterises the products, services or works provided by a specific economic operator, or to trademarks, patents, types or a specific origin or production with the effect of favouring or eliminating certain economic operators or products, services or works.

By way of derogation from the first subparagraph, such references shall only be allowed where a sufficiently precise and intelligible description of the subject-matter of the R&D procurement contract pursuant to paragraph 1 to 3 is not possible. Public buyers shall not derogate from this obligation unless justified by the subject matter of the R&D procurement contract, and in that case, the reference shall be accompanied by the words ‘or equivalent’.

Article 19

Risk benefit sharing under market conditions

1. Public buyers shall ensure that intellectual property rights to the results generated by a contractor in the performance of an R&D procurement contract do not accrue exclusively to the public buyer for its use in the conduct of its own affairs but that the public buyer shares with the contractor under market conditions the risks and benefits related to those intellectual property rights. To meet this requirement, public buyers and contractors shall fulfil the obligations set out in paragraphs 2 to 9:

2. Contractors shall have the right to retain ownership of the intellectual property rights to the results they generated in the performance of an R&D procurement contract. The R&D procurement contract shall provide this right to contractors subject to an obligation on contractors to protect their results, to use their best efforts to commercialise their results and not to use the results contrary to the public interest.

3. Contractors shall notify public buyers as soon as possible of any results that can be exploited within a maximum period from the generation of the results specified in the R&D procurement contract. This notification shall include the contractor’s decision to protect and commercialise these results. Where contractors decide not to protect or commercialise results as defined in the R&D procurement contract the public buyer shall, by derogation from paragraph 2 and without any prejudice to the moral rights of authors, have the right:

   (a) to grant, in agreement with the contractor, to the staff of the contractor the right to protect those results and obtain ownership of the intellectual property rights to those results; or

   (b) to protect itself those results, obtain itself ownership of the intellectual property rights to those results, and to transfer or license the results under fair and reasonable conditions and in a non-discriminatory way.

4. Public buyers shall obtain free access to the results generated by the contractors in the context of a R&D procurement contract for their own use and for use by their current and future contractors in the performance of any contracts awarded by those public buyers. Public buyers may also require that such free access includes in addition to usage rights other access rights such as rights to modify and maintain the results.

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5. In emergency situations where contractors are unable to satisfy subsequent demand for the results of the R&D procurement contract on the Union market, public buyers shall have the right to grant licences or to require contractors to grant licences to third parties to commercially use the results of the R&D procurement contract on a non-exclusive basis, without any right to sublicense, and under fair and reasonable conditions.

6. Where contractors fail to commercialise their results within a reasonable period as provided for in the R&D procurement contract but provide legitimate reasons for that failure, public buyers shall:

   (a) verify with the contractors whether they are able and willing to commercialise the results if given a reasonable amount of additional time;

   (b) only in case it is verified that the contractors are unable or unwilling to commercialise the results, or fail to commercialise the results within the additional time in point (a), have the right to:

      (1) grant licences or to require contractors to grant licences to third parties, under fair and reasonable conditions, to commercially use the results of the R&D procurement contract on a non-exclusive basis, without any right to sublicense ; or

      (2) only in case that a licensing action as referred to in point (a) is not sufficient to achieve the commercialisation required by the R&D procurement contract, require the contractor to transfer ownership of those results to the public buyers, under fair and reasonable conditions, without any prejudice to the moral rights of authors.

7. Where contractors fail to commercialise their results within a reasonable period provided for in the R&D procurement contract and fail to justify this with legitimate reasons or where contractors use those results in a manner contrary to the public interest, and where efforts undertaken by public buyers to obtain within a reasonable amount of time authorisation from the contractors to license the results on fair and reasonable conditions have failed, public buyers shall have the right to:

   (a) grant licences or to require contractors to grant licences to third parties to commercially use the results of the R&D procurement contract on a non-exclusive basis, without any right to sublicense without providing financial compensation to the contractors; or

   (b) in case that the action in point (a) is not sufficient to prevent the use of the results in a manner contrary to the public interest or achieve the commercialisation required by the R&D procurement contract, require the contractor to transfer ownership without of those results to the public buyers, without providing financial compensation to the contractors, without any prejudice to the moral rights of authors.

8. For the purpose of paragraph 6 and 7, legitimate reasons include where the contractor demonstrates that it used its best efforts to commercialise the results and to avoid abuse of the results in a manner that is contrary to the public interest.

9. Contractors shall notify public buyers in advance of any intention to undertake exclusive licensing or transfer of ownership of R&D procurement results. Public buyers shall have the right to object to exclusive licensing or transfer of ownership of R&D procurement results by contractors in any of the following cases:

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(a) where such licensing or transfer would negatively impact the access of the public buyer to the results or the commercial exploitation of the results;

(b) where such licensing or transfer would be contrary to the public interest in sectors of vital importance to the socio-economic or technological development of the Union or of the Member States of the public buyers;

(c) where those results would become subject to control or other restrictions by a country other than those referred to in Article 11(1), in a way that would negatively impact the access of the public buyer to or the commercialisation of the results, as referred to in point (a) of this paragraph, or in a way that would be contrary to the public interest, as referred to in point (b) of this paragraph.

10. For R&D procurements that are not pre-commercial procurements, by way of derogation from paragraphs 1 to 9, where justified by any of the following overriding reasons of public interest which shall be specified in the procurement documents, public buyers may obtain the ownership of the intellectual property rights to the results generated by contractors in the context of an R&D procurement contract:

(a) where necessary and justified for ensuring the protection of the security and public safety interests of the Union or one or several of its Member State within the meaning of Article 28(2);

(b) where necessary to prevent abuse of the results by contractors or other third parties and there is no other effective way to prevent such abuse.

(c) where the public buyer intends to have exclusive rights to exploit the intellectual property rights to the results generated by contractors;

Where public buyers obtain ownership of intellectual property rights in accordance with the first subparagraph:

(a) if they fail to exploit intellectual property rights obtained under point (c) of paragraph 8 within a period of four years from the date of obtaining the ownership of the intellectual property rights, they shall offer to transfer the ownership of those intellectual property rights or licence them under fair and reasonable conditions and in a non-discriminatory manner to any interested economic operators on the market;

(b) if they decide to transfer the ownership of these intellectual property rights or licence them, they shall do so under fair and reasonable conditions and in a non-discriminatory manner to all interested economic operators on the market;

(c) they shall ensure that all results which do not give rise to intellectual property rights may be widely disseminated, without prejudice to confidentiality and data protection obligations a referred to in Article 26.

The Commission is empowered to adopt delegated acts in accordance with Article 39 to amend the list of cases set out in this paragraph.

11. Public buyers shall:

(a) require contractors to stipulate in subcontracting agreements, that subcontractors are bound by the same intellectual property rights and obligations as those applicable to contractors under the R&D procurement contract. Public buyers shall require contractors to ensure that in any transfer or licensing agreement the contractor's obligations under the R&D procurement contract are passed on to the new owner or licensee and that the new owner or

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licensee has the obligation to pass them on in any subsequent transfer or licensing.

(b) when drawing up and implementing obligations affecting the protection of intellectual property rights in the context of R&D procurement contracts, comply with the applicable Union law on intellectual property, the TRIPS agreement[25] and other international obligations of the Union or the Member States concerned. Where participation in the R&D procurement is not restricted to economic operators that have their origin in Member States, public buyers shall treat economic operators having their origin in other WTO Member countries no less favourable than economic operators that have their origin in the public buyer's own country with regard to the protection of intellectual property, except where otherwise provided for in the TRIPS Agreement[26].

Article 20

Contract modifications

1. Public buyers may modify R&D procurement contracts without launching a new R&D procurement procedure where that possibility, irrespective of the modifications' monetary value, has been provided for in the initial procurement documents in clear, precise and unequivocal review clauses, which may include price revision clauses or options. Such clauses shall state the scope and nature of possible modifications or options as well as the conditions under which they may be used. Such clauses shall not provide for modifications or options that would alter the overall nature of the R&D procurement contract.

2. Where the possibility for modification of contracts has been provided for in the initial procurement documents, public buyers may also modify awarded contracts during their term without a new award procedure provided that the modification is not substantial within the meaning of paragraph 3 or where the modification is substantial but falls within any of the cases listed in paragraph 4, and provided that the modification responds to objective needs arising during the performance of the contract, is limited to what is necessary and appropriate for ensuring its performance and continuity, and does not alter the essential terms of the contract as initially awarded.

3. A modification shall be considered substantial where:

(a) the modification introduces conditions which, had they been part of the initial procurement procedure, would have allowed for the admission of other candidates than those initially selected or for the acceptance of a tender other than that originally accepted or would have attracted additional participants in the procurement procedure;

[25] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), set out in Annex 1C to the Agreement establishing the World Trade Organization, OJ L 336, 23.12.1994, p. 214, ELI: http://data.europa.eu/eli/agree_internation/1994/800(16)/oj.

[26] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), set out in Annex 1C to the Agreement establishing the World Trade Organization, OJ L 336, 23.12.1994, p. 214, ELI: http://data.europa.eu/eli/agree_internation/1994/800(16)/oj.

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(b) the modification changes the economic balance of the contract or the framework agreement in favour of the contractor in a manner which was not provided for in the original contract as a consequence of either;

(c) the modification extends the scope of the contract or framework agreement considerably;

(d) a new contractor replaces the one to which public buyers had initially awarded the contract in other cases than those provided for under paragraph 4, point (c).

4. Provided that they do not alter the initial economic balance of the contract in favour of the contractor in a manner which was not provided for in the initial contract or framework agreement, substantial modifications which were not provided for in the initial contract or framework agreements shall be permissible within the meaning of paragraph 2 only in the following cases:

(a) where additional works, services, or supplies have become necessary during performance of the contract, and a change of contractor is not technically or economically feasible, including due to interdependence with existing works or services or substantial increase of costs;

(b) where the modification is necessary due to circumstances which could not reasonably be anticipated by a diligent public buyer at the time of the award of the contract, and which significantly affect the performance or feasibility of the contract, including:

(a) substantial changes in the applicable regulatory or legal framework;

(ii) major technological developments;

(iii) severe disruptions, emergencies or crises with significant economic, societal or operational impact;

(c) where the original contractor is replaced by another entity:

(i) where, following a merger, takeover, acquisition, insolvency or other corporate restructuring, another economic operator succeeds, wholly or partly, to the rights and obligations of the initial contractor and where the new entity meets the original qualitative criteria; provided that this does not entail other substantial modifications to the contract and is not aimed at circumventing the application of this Regulation; or

(ii) in the event that the public buyer itself assumes the main contractor's obligations towards its subcontractors where this possibly is provided for under national legislation.

5. Before modifying the contract, the public buyer shall establish, on the basis of objective and verifiable elements, that the conditions set out in paragraph 2 are satisfied. Public buyers shall maintain detailed written records with respect to the essential elements of the modification, including its justification, its necessity or appropriateness, and its impact on the allocation of risks and economic advantages, to justify decisions relating to the modification and to enable verification of compliance with this Article by competent supervisory, audit and review bodies.

6. Before any modification of a contract that exceeds 50 % of the initial estimated value of the contract, the public buyers shall publish a contract modification notice to that effect. Such notice shall contain the justification for the modification without a new award procedure. Where several successive modifications are made that individually

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exceed 50 % of the initial estimated value of the contract, this obligation shall apply to each of such modifications. Consecutive modifications shall not be aimed at circumventing this Regulation.

For the purpose of the calculation of the initial estimated value referred to in subparagraph 1, the updated value shall be the reference value when the contract includes an indexation clause. If the contract does not include an indexation clause, the updated value shall be calculated taking into account the average inflation in the Member State of the public buyer.

7. Where public buyers substantially modify a contract pursuant to paragraph 4, and the modification does not exceed 50 % of the initial estimated contract value of the contract, they shall publish a contract modification notice within 30 days after the modification was made.

8. Modifications of a contract shall not be used to remedy deficiencies in the performance of the contract.

Article 21

Value engineering

1. Public buyers shall insert a value engineering clause in all R&D procurement contracts subject to this Regulation with an estimated value net of VAT exceeding:

   (a) EUR 10 million from [*OP please insert date 1 year from the date of entry into force of this Regulation*];

   (b) EUR 9 million from [*OP please insert date 2 years from the date of entry into force of this Regulation*];

   (c) EUR 8 million from [*OP please insert date 3 years from the date of entry into force of this Regulation*];

   (d) EUR 7 million from [*OP please insert date 3 years from the date of entry into force of this Regulation*];

   (e) EUR 6 million from [*OP please insert date 4 years from the date of entry into force of this Regulation*];

   (f) EUR 5 million from [*OP please insert date 5 years from the date of entry into force of this Regulation*].

   Public buyers may include a value engineering clause in R&D procurement contracts with a lower estimated value.

2. Public buyers shall include in the R&D procurement contract:

   (a) value engineering clauses that encourage contractors to submit value engineering change proposals (‘voluntary value engineering clauses’); or

   (b) value engineering clauses that require contractors to submit to the public buyer value engineering change proposals at regular intervals throughout the performance of the R&D procurement contract (‘mandatory value engineering clauses’).

   Public buyers may use the mandatory value engineering referred to in the first subparagraph, point (b), for the entire R&D procurement contract or only for parts of the R&D procurement contract.

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Where public buyers use mandatory value engineering for parts of the R&D procurement contract, they shall formulate, in the procurement documents, the requirements related to those parts as functional or performance requirements.

Contractors shall include corresponding mandatory or voluntary value engineering clauses in any subcontracting agreement exceeding the values referred to in paragraph 1 on the date of conclusion of the subcontracting agreement. They may include corresponding mandatory or voluntary value engineering clauses in subcontracting agreements below those values.

3. Where contractors submit value engineering change proposals, they shall include in those proposals:

(a) all the proposed changes to any of the research and development services procured as a part of the R&D procurement

(b) a description of any impacts that the proposed changes referred to in point (a) of this paragraph may have on the rights and obligations of the parties to the R&D procurement contract, including on the price of different parts of the R&D procurement contract as referred to in paragraph 2, second subparagraph, or on the tasks of the contractor;

(c) an evidence-based analysis of the expected cost and benefit of the proposed changes;

(d) in the case of subcontracting, any value engineering change proposals from their subcontractors, which are necessary for implementing the contractor's value engineering change proposal

4. Public buyers shall not accept value engineering change proposals that:

(a) alter the subject matter of the R&D procurement contract;

(b) impair essential functions or characteristics of the R&D services procured or their intended results as described in the functional or performance requirements;

(c) involve a change in deliverable quantities of the procured R&D services and their intended results only;

(d) involve a change in research and development end items or research and development test quantities that result solely from previous testing under the R&D procurement contract.

5. Public buyers shall specify in the procurement documents that they may approve amendments that may decrease or increase the price of the R&D procurement contract following a value engineering change proposal from the contractor. The procurement documents shall specify the limits of allowed increases in the price of the R&D procurement contract due to contract amendments for value engineering. Any such contract amendments for value engineering shall be carried out in accordance with Article 20.

6. Public buyers shall set out in the procurement documents incentive sharing rates that share between public buyers and contractors any net cost savings realised for public buyers from accepted value engineering change proposals on the ongoing R&D procurement contract. Where a value engineering change proposal creates net cost savings for public buyers on potential future R&D procurement contracts, the procurement documents shall specify whether the public buyer will pay the

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contractor's share of contract savings as a single payment or as a series of payments over time as future R&D procurement contracts are awarded. Public buyers shall ensure that the contractor's share of cost savings that it pays to the contractor as part of the R&D procurement does not equal to or exceed the cost of research and development services performed as part of the R&D procurement contract.

7. Public buyers may unilaterally accept or reject any value engineering proposal, in whole or in part. If the public buyer does not accept a value engineering change proposal, the public buyer shall notify the contractor in writing, explaining the reasons for the rejection. The contractor may withdraw any value engineering change proposal, in whole or in part, at any time before it is accepted by the public buyer. Until a contract amendment applies a value engineering change proposal to the ongoing R&D procurement contract, the contractor shall continue performing in accordance with the existing R&D procurement contract.

Article 22

Multiple sourcing

1. Public buyers shall apply multiple sourcing in R&D procurement procedures and shall award multiple R&D procurement contracts to multiple contractors.

2. Public buyers shall indicate in the procurement documents the minimum number of R&D procurement contracts that are expected to be awarded in accordance with paragraph 1.

3. R&D procurement contracts under multiple sourcing shall be awarded and signed in the order of the ranked list of tenders from the highest to the lowest score based on their evaluation in accordance with Article 11 unless there are duly justified reasons to proceed otherwise, in full compliance with the principles of equal treatment and transparency. All R&D procurement contracts shall be awarded within the same R&D procurement procedure.

4. To determine the number of R&D procurement contracts to be awarded in accordance with paragraph 1, public buyers shall take into account the need to:

   (a) avoid the over-reliance on a single or a limited number of contractors for products, works or services that are essential to the public buyer' internal or external operations, or for products, works or services that are based on critical technologies or critical raw materials;

   (b) reduce technology or innovation risks including by stimulating the development, testing or integration of alternative results from different contractors;

   (c) tackle situations where there is not sufficient competition on the market or prevent or reduce supplier lock-in by stimulating more competition on the market;

   (d) mitigate service disruptions and single point of failure by ensuring technical redundancy in the public buyer's infrastructure, network or service delivery system;

   (e) where necessary and justified for protection of the security and public safety interests of the Union or one or several of its Member States within the meaning of article 28(2), reserve a minimum number of R&D procurement contracts for

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economic operators originating in Member States in accordance with Article 11, paragraph 6.

5. By way of derogation from paragraph 1, where justified by any of the following reasons, which shall be specified in the procurement documents, public buyers may award a single R&D procurement contract without applying multiple sourcing in accordance with this Article:

(a) R&D procurement procedures which have as their only subject the procurement of research and development consultancy services covered by CPV codes 73200000-4 to 73220000-0;

(b) in R&D procurements that are not pre-commercial procurements, where any of the following conditions are fulfilled:

(1) the results of the outcomes of the market consultation referred to in Article 9 and market research indicate that the market is too small for multiple contractors to participate in the R&D procurement procedure;

(2) the long-term benefits of multiple sourcing as listed in paragraph 4 of this Article do not outweigh the extra costs for the public buyer applying multiple sourcing;

(3) the award of a single R&D procurement contract is necessary and justified for ensuring the protection of the security and public safety interests of the Union or one or several of its Member States within the meaning of Article 28(2);

The Commission is empowered to adopt delegated acts in accordance with Article 39 to amend the list of cases set out in the first subparagraph of this paragraph.

Article 23

R&D procurement call for tenders

1. Public buyers shall announce the launch of the call for tenders for the R&D procurement by means of a contract notice. That notice shall:

(a) be published in the *Official Journal of the European Union* and, after that, be published also on the national procurement portal of the Member State of the public buyer;

(b) contain the following elements:

(1) references to the relevant CPV codes for research and development services

(2) an indication, where relevant, that the call for tenders relates to innovation by marking the field 'innovation' in the contract notice and by including, where applicable, the words 'Pre-Commercial Procurement' in the field 'title of the procurement';

(3) the estimated value of the R&D procurement calculated pursuant to the methodology laid down in Article 10, paragraph 5.

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2. Public buyers shall widely promote the launch of the R&D procurement call for tenders to the market. To this effect, after announcing the launch of the call for tenders by means of a contract notice, public buyers may publish and promote the launch of the call for tenders through any widely available media.

3. By way of derogation from paragraph 1 and 2 of this Article, where necessary and justified for ensuring the protection of the security or public safety interests of the Union or one or several of its Member States within the meaning of Article 28(2), public buyers shall publish and promote the contract notice omitting all sensitive information and requesting economic operators to express their interest to submit tenders for the R&D procurement. Sensitive information shall be sent only to economic operators who have expressed an interest, meet the selection criteria and do not pose a security risk within the meaning of Article 28(4), point (d).

4. By way of derogation from paragraphs 1 and 2 of this Article, where the publication of a contract notice referred to in paragraphs 1 and 2 of this Article and the publication of other elements in the procurement documents referred to in Article 10 would be contrary to the security and public safety interests of the Union or one or several of its Member States within the meaning of Article 28(2), public buyers shall invite to tender and share the procurement documents only with potentially suitable economic operators who have been identified during the market consultation referred to in Article 9 and during market research, meet the qualification criteria and do not pose a security risk within the meaning of Article 28(4), point (d).

5. The minimum time limit for receipt of tenders shall be 60 days from the date on which the contract notice was sent for publication in the *Official Journal of the European Union*. Public buyers shall complete the evaluation of the tenders and notify tenderers of the award decision within 60 days from the deadline for the reception of the tenders.

6. Public buyers shall verify, based on the information in the tender, which tenderers have access to the R&D procurement in accordance with the conditions laid down in Article 11.

7. Without prejudice to Article 15(9), public buyers shall evaluate all tenders submitted by tenderers that have access to the R&D procurement on the basis of objective and non-discriminatory criteria by applying the applicable exclusion grounds and selection criteria laid down in Articles 8 and 9, the minimum requirements to be met by all tenderers and the applicable award criteria, including the innovation-related award criteria referred to in Article 17(1), and they shall draft a ranked list of evaluated tenders.

8. After the submission of the initial tenders, public buyers may conduct negotiations in one or several rounds. After each round, the economic operators participating in the negotiations shall be invited to submit a revised tender and public buyers may decide to reduce the number of participants based on the award criteria set pursuant to article to. Public buyers shall inform economic operators when a new round of negotiations will start and whether or not they will be invited. Economic operators may submit revised tenders depending on the outcome of the negotiations. Where a public buyer has decided to end the negotiations and proceed to the award of the R&D procurement contract, it shall invite the remaining economic operators to submit a final tender. Where public buyers exercise the option of reducing the number of economic operators participating in the negotiations, they shall ensure that in any given round of negotiations the number of participating economic operators

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allows for genuine competition amongst solutions discussed or participating economic operators.

9. Not later than 30 days after the conclusion of the R&D procurement contract, public buyers shall publish a contract award notice in the *Official Journal of the European Union* and, after that, also on their national procurement portal, except where the publication would be contrary to the security or public safety interests of the Union or one or several of its Member States within the meaning of Article 28(2).

   The contract award notice shall indicate that the procedure concerns an R&D procurement and relates to innovation. The public buyer shall include, where applicable, the words 'pre-commercial procurement' in the field 'title of the procurement' and shall mark the field 'innovation' in the contract award notice.

The contract award notice shall include information on the value of the awarded contracts and any awarded lots.

Article 24

Competitive development in phases and assessment of contract performance

1. Public buyers shall organise the R&D procurement in multiple successive research and development phases that may include any combination of fundamental research, industrial research and experimental development activities.

2. Public buyers may organise fast-track R&D procurement that combine any of the phases related to development and testing that are part of industrial research and experimental development into a single phase.

3. Public buyers shall organise the R&D phases in a way to ensure that the minimum number of contracts for each phase of the R&D procurement allows for genuine competition between economic operators.

4. During each R&D phase, public buyers shall assess any value engineering change proposals and, where needed, amend ongoing R&D procurement contracts accordingly in accordance with the provisions on value engineering laid down in Article 21.

5. At the end of each research and development phase of the R&D procurement, public buyers shall assess the performance of contractors on the basis of the innovation-related key performance indicators referred to in Article 24(13) .

6. The assessment shall determine whether the contractor has successfully completed the specific research and development phase based on whether the results of that specific phase are innovative, capable of meeting the requirements and commercially viable.

7. Where the assessment determines that the contractor has not successfully completed a specific phase, the public buyer may terminate the R&D procurement contract with that contractor. However, where such contractor has satisfactorily performed all the requested tasks and submitted all the requested deliverables, that contractor shall be eligible for the payment applicable for the specific phase as agreed in the R&D procurement contract.

8. Where under an R&D procurement contract, contractors have implemented value engineering change proposals that have resulted in net cost savings for the public

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buyer, the public buyer shall pay the contractor its share of those savings in accordance with the agreed value engineering payment method.

9. By terminating R&D procurement contracts at the end of a phase as referred to in paragraph 7 and by selecting the best offers for the next phase, the public buyer may reduce the number of contractors after the completion of each phase.

10. Where despite best efforts of the public buyer to ensure competitive development across all phases referred to in paragraph 3, the public buyer receives insufficient good quality offers to allow for the selection of more than one contractor for a particular phase, the public buyer may allow economic operators who have not participated in previous phases to submit tenders only for the remaining phase or phases with a view to concluding specific contracts. Where the public buyer wants to make use of this option, the public buyer shall keep the possibility for economic operators that have not participated in previous phases to express their interest to participate in later phases of the R&D procurement, up to the moment of selection of contractors for the last R&D phase. Any such economic operators shall be selected based on the same exclusion grounds, selection criteria, minimum requirements and award criteria as other contractors that participated in previous phases.

11. Where despite best efforts of the public buyer to ensure competitive development across all phases referred to in paragraphs 3 and 10, the public buyer receives insufficient good quality offers to allow for the selection of multiple contractors for the next phase, the public buyer may proceed to the next phase with only one contractor.

12. By way of derogation from paragraph 1 to 11, where justified by any of the following reasons which shall be specified in the procurement documents, public buyers may decide not to organise the R&D procurement procedure in multiple successive research and development phases:

    (a) for R&D procurement procedures which have as their only subject the procurement of research and development consultancy services covered by CPV codes 73200000-4 to 73220000-0 and

    (b) for R&D procurements that are not pre-commercial procurements, whose subject matter concerns R&D services that are limited to one technology readiness level and those R&D services are too narrow in scope to split the R&D over multiple phases.

The Commission is empowered to adopt delegated acts in accordance with Article 39 to amend the list of cases set out in the first subparagraph of this paragraph.

13. Public buyers shall:

    (a) regularly assess the performance of contractors on the basis of innovation-related key performance indicators that include keeping to the time schedule, keeping the costs under control and delivering the expected quality in terms of achievement of the minimum requirements referred to in Article 10(1), point (f), the functional requirements or performance requirements referred to in Article 18, and the award criteria, including the innovation-related award criteria, referred to in Article 17.

    (b) where, following the assessment referred to in the first subparagraph, it concludes that contract performance does not comply with the innovation-related key performance indicators, request the contractors to take corrective

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action to reach the contract performance agreed in the R&D procurement contract. Where a contractor does not take the necessary corrective actions, public buyers may terminate the R&D procurement contract with that contractor.

(c) where value engineering is used to improve contract performance throughout the R&D procurement pursuant to Article 21, take accepted value engineering proposals into account when assessing contract performance and when paying the contractor its share of cost savings that result from accepted value engineering proposals.

Article 18

Payments

1. Public buyers shall ensure the timely payment of contractors and, where applicable, subcontractors, in accordance with Directive 2011/7/EU.

2. The payment periods set by public buyers shall not exceed the time limits laid down in Article 4(3) of Directive 2011/7/EU. Where a Member State has established longer deadlines in accordance with Article 4(4) of Directive 2011/7/EU, those deadlines shall apply.

3. Public buyers shall not exceed the deadlines set out in paragraph 2 of this Article, unless otherwise expressly agreed in the R&D procurement contract and provided it is objectively justified in the light of the particular nature or features of that contract, and that in any event does not exceed 60 calendar days.

4. Upon the expiry of the period defined in paragraph 2 or 3, economic operators shall be entitled to statutory interest for late payment as defined in Article 4(1) of Directive 2011/7/EU.

5. As part of the conditions for the performance of the R&D procurement contract, public buyers may provide that the contractors pass equivalent payment terms applicable under paragraphs 2 to 4 through the supply chain.

6. Unless justified by an overriding interest of the public buyer, public buyers shall provide for an advance payment to the contractor of 30 % of the contract value.

7. At the request of a subcontractor and where the nature of the R&D procurement contract so allows, the public buyer shall transfer due payments directly to the subcontractor. Such measures may include appropriate mechanisms permitting the main contractor to object to undue payments. The arrangements concerning that mode of payment shall be set out in the procurement documents.

Article 26

Confidentiality and data protection

1. Without prejudice to the applicable Union and national law, public buyers shall not disclose without prior written agreement information provided to them by economic operators in market consultations, by tenderers during or after the call for tenders, by contractors during contract performance or by former contractors after the end of the R&D procurement, which such economic operators have designated as confidential, including technical or trade secrets and the confidential aspects of tenders. Tenderers,

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contractors or former contactors shall also not disclose without prior written agreement information provided to them by public buyers, which public buyers have designated as confidential. The prior written agreement shall not take the form of a general waiver but shall be given with reference to the intended communication of the specific confidential information.

2. Public buyers shall ensure compliance with the personal data protection rules laid down in Regulation (EU) 2016/679 and Directive 2002/58/EC, and in applicable national law in all exchanges and publication of information during the preliminary market consultation, call for tenders, contract performance and after completion of the R&D procurement.

3. Public buyers shall specify in the procurement documents referred to in Article 10 any requirements on the localisation of and access to the personal data processed by the contractor. Such requirements may include that:

(a) the personal data shall only be processed within the territory of those countries referred to in Article 11(1) and shall not be removed from not that territory;

(b) the data shall only be held in data centres located with the territory of those countries referred to in Article 11(1);

(c) no access shall be given to such data outside of the countries referred to in Article 11(1);

(d) the contractor may not change the location of data processing without the prior written authorisation of the public buyer;

(e) any transfer of personal data under the R&D procurement contract to third countries or international organisations shall comply fully with the requirements laid down in Regulation (EU) 2016/679.

Article 27

Termination of R&D procurement contracts

Public buyers shall terminate the R&D procurement contract where:

(a) the economic operator becomes subject of a conviction for one of the mandatory exclusion grounds referred to in Article 13(1), except where the public buyer establishes that such termination is not warranted for reasons of overriding public interest;

(b) the R&D procurement contract should not have been awarded to the contractor in view of a serious infringement of the obligations under the Treaties and this Regulation that has been declared by the Court of Justice of the European Union in a procedure pursuant to Article 258 TFEU or a competent national oversight body.

SECTION 2
SECURITY AND PUBLIC SAFETY

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Article 28

Security and public safety in R&D procurement

1. Public buyers shall take appropriate measures, where relevant at any stage of the R&D procurement procedure, from planning and market consultation to contract award and performance, to ensure the protection of the security and public safety interests of the Union or one or several of its Member States for any R&D procurement procedure falling within the scope of this Regulation identified as presenting or including a risk for security or public safety, irrespective of the contract value.

2. Security and public safety interests of the Union or a Member State relevant for a given R&D procurement contract may include the following:

   (a) protection of critical infrastructure or essential services, protection of critical supply chains, critical technologies, resilience against physical, cyber, or hybrid threats, and prevention and protection against risks of their disruption including due to harmful strategic dependencies on third-country suppliers;

   (b) prevention of espionage, sabotage or technology leakage;

   (c) crisis preparedness, including business continuity and contingency planning for disruptions in case of natural disasters or geopolitical instability, pandemics or cyberattacks;

   (d) the prevention of other harmful interference, including non-EU and non-EU state-controlled influence;

   (e) the cybersecurity of systems, networks, and data processed;

   (f) the protection of classified information, sensitive data, research, or intellectual property from unauthorised access or transfer;

   (g) ensuring public health, including crisis-prepared and self-sufficient health services; or

   (h) protection of the environment and protection against climate-related disruptions.

3. Risks for security and public safety in a R&D procurement contract may arise in particular from the following:

   (a) the subject matter of the R&D procurement contract, including:

      (i) sensitivity of the assets involved or to be developed in its implementation;

      (ii) access to and handling sensitive data;

      (iii) critical dependency or risk of critical dependency on a limited number of third country suppliers;

      (iv) risks associated with access to critical infrastructure, research facilities, IT systems, or critical materials;

      (v) dual-use nature of the results of research and development services procured;

      (vi) the nature of the public interests attached to it and the potential consequences of a malfunction or malperformance, such as harm to

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public safety, national security, economic stability, health security or fundamental rights.

(b) the characteristics of economic operators, including:

(i) ownership, control, or financing structure bearing risks of undue interference or influence over the economic operator;

(ii) security track record, including past breaches, non-compliance with security standards, or exclusion from other procurement procedures on security grounds;

(iii) capacity to meet applicable security clearance, personnel vetting, or information security requirements;

(iv) exposure to third-country legislation that may compel disclosure of sensitive information or interference with contract performance.

4. Public buyers shall, to the extent possible specify in the procurement documents in a clear and sufficiently detailed manner appropriate measures that are proportionate to the risks referred to in paragraph 3 and non-discriminatory. Such measures may be implemented, in particular through:

(a) specifications and market consultation documents, including mandatory security standards, certifications, personnel vetting or security clearance obligations, or risk management and assurance requirements;

(b) award criteria, such as evaluating bidders' security management systems, security compliance standards, incident response capabilities, supply chain security;

(c) contract performance clauses, including clauses enabling security oversight of suppliers through audits, inspections, or documentation reviews and implementation of corrective measures in the case of breaches, as well as provisions on subcontracting, ownership change notification, and the protection of classified or sensitive information;

(d) without prejudice to optional exclusion grounds related to security and public safety as referred to in Article 14, selection criteria, where justified, including the requirement to possess security clearances or otherwise requiring tenderers to establish that they do not present unacceptable security risks pursuant to paragraph 3, point (b) of this Article.

Public buyers may also indicate in the procurement documents which security measures they intend to implement where security risks arise during the R&D procurement procedure.

Article 29

Termination of R&D procurement contracts for security and public safety reasons

1. Without prejudice to Article 27 and the national contract law of the Member States, the public buyer may terminate a R&D procurement contract in whole or in part where it determines that the contractor has failed to comply with security obligations within the meaning of Article 28(2) or a risk to security or public safety within the meaning of Article 28(2) has materialised or is likely to materialise.

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2. The decision to terminate a contract pursuant to this Article shall be proportionate to the level of security risk. Before terminating a R&D procurement contract, the public buyer shall conduct a written assessment. The public buyer shall take into account in particular the following:

   (a) the severity of the risk to security or public safety;

   (b) the impact of termination on the delivery of public services;

   (c) alternative mitigation measures such as contract amendments or enhanced monitoring.

3. Unless justified by the severity of the risks involved, the imminence of the threat or where notification may aggravate the risk, the public buyer shall in a preparatory phase notify the contractor in writing of its intent to terminate, specifying:

   (a) the grounds for termination;

   (b) the facts and evidence supporting the decision, with the exception of classified information;

   (c) the proposed date of termination.

4. The contractor shall have at least 10 calendar days to submit observations on the grounds for termination and propose remedial actions. The public buyer may shorten the deadline in case of emergency.

5. The contractor shall cooperate with the public buyer to secure or transfer data, documents, or assets related to the R&D procurement contract and ensure continuity of critical services during the transition period.

Article 30

Cybersecurity

1. For all products with digital elements used and developed as part of the research and development services procured that fall within the scope of Regulation (EU) 2024/2847 of the European Parliament and of the Council[27], public buyers shall ensure compliance with the essential cybersecurity requirements set out in Annex I of that Regulation, including the manufacturers' ability to handle vulnerabilities effectively.

2. Without prejudice to paragraph 1 of this Article and to Directive (EU) 2022/2555 of the European Parliament and of the Council[28], public buyers may specify in the procurement documents requirements relating to cybersecurity for the research and development services procured. To that end, they may include specifications, selection criteria, award criteria or contract performance clauses. Such requirements

[27] Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act) (OJ L, 2024/2847, 20.11.2024, ELI: http://data.europa.eu/eli/reg/2024/2847/oj).

[28] Directive (EU) 2022/2555 of the European Parliament and of the Council of 14 December 2022 on measures for a high common level of cybersecurity across the Union, amending Regulation (EU) No 910/2014 and Directive (EU) 2018/1972, and repealing Directive (EU) 2016/1148 (NIS 2 Directive) (OJ L 333, 27.12.2022, p. 80, ELI: http://data.europa.eu/eli/dir/2022/2555/oj).

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shall be linked to the subject matter of the R&D procurement contract and comply with the principles of transparency, non-discrimination and proportionality.

SECTION 3
JOINT PROCUREMENT OF RESEARCH AND DEVELOPMENT SERVICES

Article 31

Common rules on joint R&D procurement

1. Public buyers shall carry out joint R&D procurement in accordance with the rules laid down in this Regulation.

2. Where two or more public buyers from one or more Member States wish to conduct a joint R&D procurement, they shall conclude a joint procurement agreement establishing a buyers' group and appointing the lead buyer. That agreement shall specify at least the following:

   (a) the financial commitments provided by each public buyer in the buyers' group for the joint R&D procurement;

   (b) the division of roles and responsibilities between the lead buyer and the public buyers that are members of the buyers' group regarding the R&D procurement procedure, contract performance and post-contract interactions with former contractors as referred to in Chapter 2, Section 1 and 2;

   (c) the applicable Union or national law related to dispute resolution, related to any procedures or approvals needed for testing prototypes or first products, services or works developed during the R&D procurement and any other aspects of the conduct of the joint R&D procurement that are not governed by this Regulation;

   (d) the mechanism for the allocation and exploitation of the results of the joint R&D procurement.

In addition to the elements listed in Article 10, the procurement documents for joint R&D procurement shall include the information referred to in the first subparagraph, points (b), (c) and (d), of this Article.

3. The members of the buyers' group shall jointly provide the financial commitments for the R&D procurement and jointly conduct the market consultation, draft procurement documents for their common R&D procurement and carry out the evaluation of tenders.

5. The lead buyer shall launch the joint R&D procurement procedure and award the R&D procurement contracts in the name and on behalf of all public buyers that are members of the buyers' group. Public buyers that conduct joint R&D procurement may do so in any of the official languages of the Union and they may allow tenderers to submit tenders in any of those official languages.

6. Public buyers may organise joint R&D procurement through central purchasing bodies.

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7. Central purchasing bodies, which may be a Member State entity, may carry out the following R&D procurement related activities, where they indicate that they act as a central purchasing body:

(a) acting as a wholesaler by buying and re-selling R&D services procured on the market;

(b) acting as an intermediary, by publishing notices and awarding R&D procurement contracts for other public buyers;

(c) carrying out or taking part in joint R&D procurement activities conducted under this Regulation or Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council[29] where such joint procurement is provided for by this Regulation or other Union acts;

(d) providing ancillary R&D related procurement support services to public buyers, including technical assistance, infrastructure or advice.

Any public buyer may procure R&D services and obtain their intended results from or through any central purchasing body established in the Union offering centralised purchasing activities. A public buyer shall be deemed to fulfil its obligations pursuant to this Regulation when it procures research and development services from or through a central purchasing body. Central purchasing bodies that are not themselves a public buyer shall conduct R&D procurement procedures in accordance with this Regulation.

8. Union institutions, bodies or agencies may carry out R&D procurement, including pre-commercial procurement, for themselves, jointly with or on behalf of other Union entities and jointly with or on behalf of public buyers in Member States. In accordance with paragraph 7, point (c), the Commission shall establish the rules governing R&D procurement activities referred to in this paragraph by means of delegated acts adopted under Article 39.

Chapter 3
COMMERCIALISATION OF RESEARCH AND INNOVATION RESULTS

Article 32

Union Competence Centre for intellectual property-backed finance and commercialisation of intellectual property assets

1. The European Union Intellectual Property Office (‘the Office’) shall establish a Competence Centre to support and promote intellectual property-backed finance and commercialisation of intellectual property, including intellectual property resulting from research and innovation (‘the Competence Centre’)

2. The Competence Centre shall support the following entities through its tasks:

(a) researchers established in a Member State;

[29] Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union (OJ L, 2024/2509, 26.09.2024, ELI: http://data.europa.eu/eli/reg/2024/2509/oj).

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(b) innovative enterprises established in a Member State, including innovative startups, innovative scaleups and spin-offs, whose innovative and competitive performance is driven by the ownership or use and commercialisation of intellectual property rights;

(c) other public and private entities established in a Member State that have an interest in the commercialisation of intellectual property assets;

(d) entities whose function is to support any of the entities referred to in points (a), (b) and (c).

3. To improve access to finance for the entities referred to in paragraph 2, the Office through the Competence Centre shall:

(a) by [*OP please insert date 4 years from the date of entry into force of this Regulation*], develop a voluntary Union framework for the valuation and disclosure of intellectual property assets based on all types of intellectual property rights and designed to facilitate its use across different sectors and its uptake by financial stakeholders, where possible making use of the European Business Wallets established in accordance with *[Regulation XXX of the European Parliament and of the Council on the establishment of European Business Wallets]*, including by:

(i) setting up and maintaining digital processes and services related to the disclosure, screening and valuation of intellectual property assets;

(ii) identifying and compiling best practices to support the development of the voluntary valuation framework;

(iii) establishing, as an integral part of the framework, a voluntary disclosure arrangements enabling undertakings to present information on their intellectual property assets in a comparable and structured manner for financing purposes.

(b) by [*OP please insert date 4 years from the date of entry into force of this Regulation*], establish and maintain, in close cooperation with the Commission, a Union-wide digital match-making platform, where possible making use of the European Business Wallets, to facilitate, on a voluntary basis, the licensing and transfer of intellectual property rights protected in the Union.

(c) facilitate the development of a secondary market to support the disposal of intellectual property assets held by the entities referred to in paragraph 2;

(d) support the relevant public and private financial stakeholders, including Union institutions, bodies, offices and agencies, as well as financial institutions and commercial banks, in defining and implementing new public and private financial instruments backed by intellectual property, including the provision of sound evidence on market needs, the analysis of data stemming from the implementation of such financial instruments and the provision of IP-related technical advisory services;

(e) establish and implement skill development programmes across the innovation ecosystem in relation to intellectual property-backed finance and commercialisation of intellectual property assets;

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(f) raise awareness about intellectual property rights as a driver for the Union's innovation, growth and competitiveness and about intellectual property-backed finance;

(g) support the progressive development of an evidence database on intellectual property-backed financing, including by collecting and analysing anonymised or other non-personal data from intellectual property-backed financing transactions and, where appropriate, by establishing mechanisms to facilitate the availability and use of such data, including through the European Business Wallets;

(h) provide support to the entities defined in paragraph 2 in the valorisation and commercialisation of intellectual property resulting from publicly funded research and innovation, including through awareness raising and capacity building in management of intellectual property, providing assistance in defining intellectual property management and commercialisation strategies;

(i) coordinate a Union-level helpdesk offering information and support services related to intellectual property-backed financing to entities listed in paragraph 2.

The Commission shall, by means of implementing acts, lay down the technical specifications necessary for the uniform implementation of the voluntary Union framework referred to in the first subparagraph, point (a), of this Article, including the specifications concerning the content, comparability and interoperability of disclosures. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 38(2). The Office shall, in accordance with the technical specifications laid down pursuant to the first subparagraph, develop, maintain and, where necessary, update the templates and related operational tools for the implementation of the voluntary Union framework

The Commission shall, by means of implementing acts, lay down common technical standards, interoperability requirements and operational specifications for the digital match-making platform referred to in the first subparagraph, point (b), of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 38(2).

4. Subject to the availability of the accumulated budgetary surplus and of the approval of the Office's Budget Committee, the Office may conclude contribution agreements with the Commission for the implementation of clearly defined Union activities falling within the scope of the tasks entrusted to the Office under this Regulation and relating to intellectual property-backed finance and the commercialisation of intellectual property assets. Such contribution agreements shall specify the respective responsibilities and financial contributions of the parties, the activities and deliverables to be financed, the eligible costs, implementation arrangements, reporting obligations, internal control measures, audit rights and the treatment of any unused amounts.

5. Regulation (EU) 2017/1001 shall apply to the fulfilment of the tasks entrusted to the Office under this Article. The Competence Centre shall form part of the Office and shall not have separate legal personality, financial autonomy or decision-making powers. All activities carried out through the Competence Centre shall remain subject to the governance, programming, budgetary, accounting, internal control and reporting framework applicable to the Office.

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6. The set-up costs of the Competence Centre and the running costs arising from the tasks entrusted to the Office by this Regulation shall be covered by its operational budget. The set-up costs may include, at least, the costs related to the development of the IT support systems and the setting up of the corresponding administrative infrastructure, as well as the time-limited preparation or setting up of new initiatives. The Office's Budget Committee may authorise the use of the accumulated budgetary surplus of the Office for necessary, clearly defined, non-recurrent and time-limited set-up costs.

7. The Executive Director of the Office may introduce charges for specific services referred to in this Article provided to the entities referred to in paragraph 2 of this Article in accordance with Article 178 of Regulation (EU) 2017/1001. Such charges shall be transparent, non-discriminatory and limited to the cost of the specific service.

Access to the voluntary valuation framework developed in accordance with paragraph 3, first subparagraph, point (a), access to the digital match-making platform developed in accordance with paragraph 3, first subparagraph, point (b), support services referred to in paragraph 3, first subparagraph, point (d) provided to public stakeholders, including the Union institutions, bodies, offices and agencies, and access to the Union-level helpdesk referred to in paragraph 3, first subparagraph, point (i) shall not be subject to fees or charges.

Article 33

Data Collection

1. With a view to supporting the fulfilment of the tasks entrusted to the Office under Article 32, and in particular those relating to the development of an evidence base, the analysis of data and the support to improved access to finance for the entities referred to in Article 32(2), the Office shall collect and analyse anonymised or other non-personal data relating to transactions in which intellectual property rights are used as collateral for credit or insurance purposes or as in-kind contribution in equity investment scenarios, without prejudice to applicable rules on classified information.

2. When collecting and analysing data in accordance with this Article, the Office shall, in accordance with Union law, cooperate with Union institutions, bodies and agencies, the competent public authorities of the Member States, national and regional intellectual property offices, and relevant public and private stakeholders in the fields of finance and insurance, with a view to facilitating the availability, comparability and reuse of existing data, as well as to exploring, on the basis of existing data sources and practices, possible approaches for improving transparency and interoperability across the Union.

3. The data collected and analysed by the Office in accordance with this Article may include, where available and appropriate, information originating from intellectual property registers, business registers, registers of pledges or other rights in rem over intellectual property and similar sources, as well as other relevant information made available by public authorities or private sector actors, including information on how intellectual property used as collateral for credit or insurance purposes or as in-kind contribution in equity investment scenarios has been evaluated, on the size and characteristics of the corresponding transaction, on the type of intellectual property

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right concerned, and on relevant indicators such as equity valuation, collateralisation, or loan-to-value ratios.

4. In order to support the effective use of the data collected and analysed in accordance with this Article, the Office shall, in cooperation with the stakeholders concerned, promote the development of common standards and practices relating to data quality, formats and access conditions, including differentiated and proportionate access modalities, and shall provide guidance and support measures aimed at enabling innovative enterprises, innovative startups, innovative scaleups and SMEs to benefit from the improved evidence base and analytical outputs.

5. Where justified by experience gained through the activities referred to in this Article, the Office may consider, in cooperation with the stakeholders concerned, the development of digital tools or structured data systems to further support the fulfilment of the tasks of the Competence Centre set out in Article 32, including by investigating the feasibility of a Union-wide register of pledges over intellectual property assets.

6. The Office shall put in place guidance and support measures to ensure that innovative enterprises, innovative startups, innovative scaleups and SMEs can effectively benefit from the data collected in accordance with this Article.

Article 34

Intellectual property valuators

1. The persons and entities referred to in Article 32(2) and relevant public and private entities in the fields of finance and insurance may request an assessment of the value of the intellectual property rights in accordance with the voluntary framework for the valuation of intellectual property assets referred to in Article 32(3), first subparagraph, point (a). Such assessment may be carried out by an intellectual property valuator certified in accordance with this Article.

2. Where the assessment is commissioned in connection with a financing transaction, the information necessary for the assessment shall be provided in accordance with the arrangements agreed between the parties concerned and subject to applicable rules on confidentiality and the protection of trade secrets.

3. When carrying out an assessment, the valuator shall act independently and shall avoid any conflict of interest with the persons or entities concerned by the assessment.

4. The fees and other costs relating to an assessment shall be borne by the person or entity commissioning the assessment, unless otherwise agreed between the parties. They shall be transparent, reasonable and proportionate to the nature, scope and complexity of the assessment.

Article 35

Certification of intellectual property valuators

5. The Office shall establish and administer a Union certification scheme for intellectual property valuators. The certification shall attest that a valuator has acquired the knowledge and professional competence necessary to carry out

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valuations in accordance with the voluntary Union framework for the valuation and disclosure of intellectual property referred to in Article 32(3), point (a).

6. Certification under this Article shall be voluntary and shall attest competence in applying the Union valuation framework. It shall not constitute a professional licence or confer a right to exercise a regulated profession, nor shall it be a prerequisite for carrying out intellectual property valuations under Union or national law. It shall be without prejudice to national rules governing regulated professions, professional qualifications and the provision of valuation services.

7. Certification by the Office shall not make the Office responsible for individual valuations carried out by a certified valuer and shall not confer binding or presumptive legal effect on such valuations.

8. To be eligible for certification, the prospective valuator shall:

(a) possess an appropriate educational or professional background and relevant professional experience, and technical competence in the valuation of intellectual property assets;

(b) successfully complete specialised training on the application of the voluntary Union framework referred to in paragraph 1, and an assessment demonstrating sufficient knowledge and practical ability to apply that framework;

(c) demonstrate objectivity, integrity and adherence to appropriate professional standards or codes of conduct.

The training and assessment referred to in points (b) and (c) shall be organised by the Office. The Office may develop and provide them in cooperation with national intellectual property offices and relevant European or international professional organisations and valuation bodies.

9. The Commission shall, by means of implementing acts, lay down detailed conditions for the implementation of the certification scheme established by this Article, including:

(a) the minimum educational or professional background and professional experience required for admission to the certification scheme and the evidence to be submitted for that purpose;

(b) the minimum content, learning outcomes and practical components of the specialised training referred to in paragraph 2, point (b), including any requirements concerning attendance;

(c) the form, content, assessment methodology and minimum pass requirements for the assessment referred to in paragraph 2, point (c);

(d) the application procedure, including the documents and evidence to be submitted and the arrangements for verifying compliance with the conditions laid down in paragraph 2;

(e) the period of validity of the certification and the conditions and procedure for its renewal, including requirements relating to continuing professional development;

(f) the grounds and procedure for suspension and withdrawal of certification, including appropriate procedural safeguards and the right of the person concerned to be heard;

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(g) the conditions governing the use, presentation and communication of the Union certification and certified status, including rules intended to prevent any misleading representation as to the scope or legal effects of the certification; and

(h) the information concerning certified valuators to be included in the database referred to in paragraph 7 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 38(2).

10. The Office, through the Competence Centre, shall grant, renew, suspend or withdraw certification in accordance with this Article and the implementing acts referred to in the preceding paragraph.

11. The Office, through the Competence Centre, shall establish and maintain a publicly accessible Union database of intellectual property valuators certified in accordance with this Article.

12. The Executive Director may introduce charges for the certification, assessment and renewal services provided under this Article in accordance with Article 178 of Regulation (EU) 2017/1001. Such charges shall be transparent, non-discriminatory and shall not exceed the cost of the specific services concerned

Article 36

Programming and reporting

1. The Office shall reflect the activities necessary for the performance of the tasks entrusted to the Office in accordance with this Regulation in a separate section of the multiannual strategic programme and the annual work programme of the Office referred to in Article 153(1), points (a) and (b), of Regulation (EU) 2017/1001.

2. The specific section referred to in paragraph 1 of this Article shall set out the objectives, activities, expected results, performance indicators and estimated human and financial resources relating to those tasks, taking into account the relevant Union policies and priorities. The preparation, adoption, implementation and amendment of the multiannual strategic programme and the annual work programme shall be governed by Regulation (EU) 2017/1001.

3. The Office shall include in the annual report on the activities of the Office referred to in Article 153(1), point (c), of Regulation (EU) 2017/1001 a specific section on the tasks entrusted to the Office under this Article. That specific section shall contain all of the following:

(a) a review of the main activities carried out during the preceding year;

(b) the results achieved in relation to the objectives and performance indicators set out in the annual work programme;

(c) an overall assessment of the fulfilment of those tasks, including the financial and staff resources used, any revenue obtained from charges and any material effect on the performance of the other statutory tasks of the Office;

(d) an overview of the activities planned for the following years.

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Article 37

Amendment to Regulation (EU) 2017/1001

In Article 151(1) of Regulation (EU) 2017/1001**Error! Bookmark not defined.**, the following point (f) is added:

'(f) the tasks entrusted to it under Regulation (EU) 202X/XXXX of the European Parliament and of the Council. *[+]'

_____

* Regulation (EU) 202X/XXXX of the European Parliament and of the Council (OJ…, ELI…).'.

Chapter 4
FINAL PROVISIONS

Article 38

Committee procedure

1. The Commission shall be assisted by the Committee on Implementation Rules established by Regulation (EU) 2017/1001. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 39

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 11(2),19(10), 22(5), 24(12) and 31(8) shall be conferred on the Commission for a period of five years from the entry into force of this Regulation. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Articles 7(2), 19(11), 22(5), 24(12) and 31(8) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect on the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

[+] OJ: Please insert in the text the number, date, title and OJ reference of the present Regulation (European Innovation Act) in the footnote.

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4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Articles 11(2), 19(10), 22(5), 24(12) and 31(8) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 40

Evaluation

By *[OP please insert date four years from the date of entry into force of this Regulation]* and every five years thereafter, the Commission shall carry out an evaluation of this Regulation in light of the objectives that it pursues, and shall present a report thereon to the European Parliament, to the Council and to the European Economic and Social Committee.

Article 41

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*
[...]	*[...]*

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LEGISLATIVE FINANCIAL AND DIGITAL STATEMENT

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1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a framework of measures for strengthening Europe's innovation ecosystem (European Innovation Act)

1.2. Policy area(s) concerned

Single market, competitiveness, research and innovation

1.3. Objective(s)

1.3.1. General objective(s)

The general objective of the initiative is to improve the functioning of the Single Market for innovation by reducing barriers to the development, testing and scale-up of innovative solutions, thereby speeding up their commercialisation in the Union.

1.3.2. Specific objective(s)

Specific objective No 1

Lower valuation costs and increase licensing and transfer of IPs in the EU in the next 4 years.

Specific objective No 2

Increase spending on procurement of R&D services in the next 5 years.

Specific objective No 3

Increase the procurement of EU-based R&D solutions in the next 5 years.

1.3.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

Economic benefits

The introduction of a harmonised EU-wide IP valuation framework, complemented by an EU IP Training Centre and an IP matchmaking platform, is expected to reduce the costs and complexity associated with the valuation, management, and monetisation of intellectual property assets. By providing standardised valuation methodologies, specialised expertise, and improved market infrastructure, these measures would reduce information asymmetries between firms and external financiers regarding the economic value of IP assets.

Improved transparency and credibility in IP valuation are expected to facilitate the use of patents and other IP assets as collateral, thereby increasing access to both debt and equity financing. In particular, standardised valuation systems can strengthen the collateral function of IP for banks and the signalling function of IP for venture capital investors, contributing to greater volumes of IP-backed finance. As firms become better able to capture and communicate the economic value of their intellectual property, the expected returns from patenting are likely to increase, creating stronger incentives to invest in innovation and seek formal IP protection.

The literature suggests that this relationship may generate a virtuous cycle between patenting and financing. Stronger IP portfolios facilitate access to external finance,

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while improved financing conditions support additional R&D investments and innovation activities, leading to further patent generation. Beyond increasing the quantity of patent applications, more reliable valuation mechanisms may also improve patent quality by encouraging firms to focus on inventions with greater technological and commercial potential.

Several strands of evidence support this mechanism. From a real-options perspective, credible valuation systems and secondary IP markets increase the reversibility of patent-related investments by transforming patents into tradable assets rather than purely legal instruments. This reduces the effective risk of patenting and encourages firms to file patents that can subsequently be licensed, sold, or used to support financing transactions. Evidence from the United States shows that exposure to secondary patent markets increases patenting activity, particularly under conditions of economic uncertainty, while also encouraging firms to patent inventions that would otherwise be kept as trade secrets.

The introduction of a harmonised EU-level framework for R&D procurement is expected to significantly reduce the legal uncertainty and procedural complexity currently associated with R&D procurement across Member States. This is expected to facilitate the implementation of cross-border R&D procurement projects, enabling public buyers to pool demand and achieve greater critical mass, thereby unlocking the full potential of the Single Market for innovation procurement.

Embedding proven innovation-oriented procurement practices within a common framework would also improve the effectiveness and efficiency of R&D procurement processes, increasing the return on public investment in innovation. Clearer procedures would enhance public buyers' capacity to design and manage R&D procurement projects, while lowering participation costs and barriers for suppliers. This is expected to encourage a larger number of firms, including those from different Member States, to participate in R&D procurement call for tenders, thereby increasing competition, improving the quality of proposed solutions, and broadening access to innovative technologies.

Furthermore, the introduction of an EU preference within R&D procurement procedures would increase the likelihood that significant economic and technological benefits generated through publicly funded R&D procurement remain within the European Union. Strengthening demand for innovative solutions developed by EU-based firms would support private R&D investment, foster the growth of European innovation ecosystems, and contribute to the creation of high-value jobs. In doing so, it would reinforce the EU's strategic autonomy and technological sovereignty in critical technologies and sectors.

Overall, the European Innovation Act is estimated to increase EU GDP by between 0.25% and 0.42% over a ten-year horizon relative to a baseline scenario without the European Innovation Act.

Beyond its effects on GDP and employment, the European Innovation Act is expected to generate broader societal benefits by strengthening the translation of research and innovation into marketable solutions. A substantial body of empirical evidence shows that sustained public and private investment in research and innovation accelerates the development, diffusion, and cost reduction of clean technologies, contributing to lower greenhouse gas emissions, improved energy efficiency, and more sustainable production processes. These benefits are likely to

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generate positive environmental and social externalities that are only partially captured by conventional macroeconomic indicators such as GDP.

1.3.4. Indicators of performance

Specify the indicators for monitoring progress and achievements.

Progress towards the specific objective of reducing IP valuation costs and increasing the licensing, transfer, and financial utilisation of intellectual property rights (IP rights) in the EU will be monitored through several indicators. These include the number of Member States integrating the European Union Intellectual Property Office valuation standards into their national valuation practices, the number of transactions applying the EU IP valuation methodology, the average IP valuation costs borne by firms, and the number of companies using IP assets as collateral or in financing transactions.

Progress towards the specific objective of increasing expenditure on the procurement of R&D services will be measured by the share of R&D expenditure in total public procurement and the number and value of cross-border R&D procurement contracts. Progress towards the specific objective of increasing the procurement of EU-based R&D solutions will be monitored through the number and value of R&D procurement contracts awarded to EU-based suppliers and solutions.

1.4. The proposal/initiative relates to:

☒ a new action

☐ a new action following a pilot project / preparatory action[30]

☐ the extension of an existing action

☐ a merger or redirection of one or more actions towards another/a new action

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative

The proposal responds to the need to address the existing fragmentations in the Single Market in the field of **R&D procurement** by establishing a harmonised procedure for R&D procurements and joint cross-border R&D procurements to be implemented by public buyers in all Member States in accordance with this Regulation once it enters into force.

Furthermore, the entrusts new tasks to the European Union Intellectual Property Office, including the establishment of a European Union Competence Centre for **intellectual property-backed finance and commercialisation of intellectual property** once the Regulation enters into force. Once established within the European Union Intellectual Property Office, the Competence Centre will start discharging the tasks conferred upon it by the Regulation including providing support to various stakeholders in the fields of intellectual property-backed financing and commercialisation of intellectual property assets. Finally, by 1 September 2028 (to be intended as tentative date, as IT development require time), the European Union Intellectual Property Office, through the Competence Centre, will develop a valuation framework for all intangible assets and establish a digital matchmaking

[30] As referred to in Article 58(2), point (a) or (b) of the Financial Regulation.

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platform to facilitate the licensing and transfer of all types of intellectual property rights protected at Union level.

1.5.2. Added value of EU involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities).

For the purposes of this section 'added value of EU involvement' is the value resulting from EU action, that is additional to the value that would have been otherwise created by Member States alone.

Reasons for action at EU level (ex-ante)

The proposed measures focus on areas where there is clear added value in acting at Union level due to the scale, speed and scope of the efforts needed. Actions aim at improving the business case for innovators to bring innovations to the market by facilitating the valuation, commercialisation and use of IP rights as a collateral to obtain IP-backed finance and by making it easier to find first customers through R&D procurement. It enhances efficiency by enabling better cross-border cooperation, ensures fairer access to opportunities for innovative companies irrespective of their location, and strengthens the Union's capacity to compete globally.

Expected generated EU added value (ex-post)

EU intervention will generate lasting benefits through economies of scale, lower transaction costs, and improved legal certainty for public buyers, companies and investors. It will strengthen Europe's capacity to place innovative solutions on the market and to commercialise intellectual property assets and leverage them in company financing. Harmonised and digitalised procedures for R&D procurement will reduce transaction costs and administrative burden for public buyers and companies participating in R&D procurements, while providing uniform market conditions across Member States. Establishment of the Competence Centre within the European Union Intellectual Property Office will increase the uptake of intellectual property-backed financing in Europe, increasing financing opportunities for innovative companies.

1.5.3. Lessons learned from similar experiences in the past

The European Union Intellectual Property Office has gathered a significant expertise in the field of IP rights through its tasks related to the protection of EU trademarks, designs and geographic indications, as well as monitoring infringements of all types of intellectual property rights through the European Observatory on Infringements of Intellectual Property Rights. Taking into account this experience, the proposal builds on European Union Intellectual Property Office's expertise by entrusting to it additional tasks related to valuation and commercialisation of IP.

The Innovation Partnership procedure, which was introduced in the 2014 EU public procurement directives, is used only to a very limited extent. The evaluation of the 2014 EU public procurement directives concluded that in the ongoing revision of the EU public procurement directives the obligation that this procedure must involve the procurement of R&D should be removed, because public buyers do not like buying R&D as part of a procedure that buys commercial volumes of solutions and that is open to providers from all third countries with who the Union has an international agreement on public procurement. Taking into account this experience, the European the proposal aims to provide a procedure for **R&D procurement** for buying R&D

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services that does not involve the procurement of commercial volumes of solutions and that can be open only to providers from Member States, EEA countries and Western Balkan countries.

1.5.4. Compatibility with the multiannual financial framework and possible synergies with other appropriate instruments

The proposal is fully consistent with the 2021-2027 Multiannual Financial Framework and will be implemented through existing Union programmes without creating new spending envelopes or financial obligations beyond existing resources.

Should the co-legislators approve the proposal and decide that the EUIPO sets up, runs the Center and contributes funds (either from the operational or the surplus), it should be noted that this EUIPO contribution would not come from the EU budget (it is not EU contribution) but from the EUIPO's budget and therefore, it does not depend on the MFF.

In that sense, the decision on the specific budgetary elements would be subject to the decision and approval of the Management Board and Budgetary Committee (MBBC) of the EUIPO.

1.5.5. Assessment of the different available financing options, including scope for redeployment

All financing will be ensured through redeployments from programmes. Without prejudice to the outcome of negotiations on the next MFF, the appropriations foreseen from 2028 onwards are strictly indicative.

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1.6. Duration of the proposal/initiative and of its financial impact

☐ **limited duration**

– ☐ in effect from [DD/MM]YYYY to [DD/MM]YYYY

– ☐ financial impact from YYYY to YYYY for commitment appropriations and from YYYY to YYYY for payment appropriations.

☒ **unlimited duration**

– Implementation with a start-up period from YYYY to YYYY,

– followed by full-scale operation.

1.7. Method(s) of budget implementation planned[31]

☒ **Direct management** by the Commission

– ☐ by its departments, including by its staff in the Union delegations;

– ☐ by the executive agencies

☐ **Shared management** with the Member States

☐ **Indirect management** by entrusting budget implementation tasks to:

– ☐ third countries or the bodies they have designated

– ☐ international organisations and their agencies (to be specified)

– ☐ the European Investment Bank and the European Investment Fund

– ☐ bodies referred to in Articles 70 and 71 of the Financial Regulation

– ☐ public law bodies

– ☐ bodies governed by private law with a public service mission to the extent that they are provided with adequate financial guarantees

– ☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that are provided with adequate financial guarantees

– ☐ bodies or persons entrusted with the implementation of specific actions in the common foreign and security policy pursuant to Title V of the Treaty on European Union, and identified in the relevant basic act

– ☐ bodies established in a Member State, governed by the private law of a Member State or Union law and eligible to be entrusted, in accordance with sector-specific rules, with the implementation of Union funds or budgetary guarantees, to the extent that such bodies are controlled by public law bodies or by bodies governed by private law with a public service mission, and are provided with adequate financial guarantees in the form of joint and several liability by the controlling bodies or equivalent financial guarantees and which may be, for each action, limited to the maximum amount of the Union support.

[31] Details of budget implementation methods and references to the Financial Regulation may be found on the BUDGpedia site: https://myintracomm.ec.europa.eu/corp/budget/financial-rules/budget-implementation/Pages/implementation-methods.aspx.

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2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

This Statement includes staff expenditures. Standard rules for this type of expenditure apply. The Commission will evaluate the output, results and impact of this proposal every three years after the date on which it becomes applicable. The evaluation will assess the contribution of this Regulation to the functioning of the single market, including the objectives specified in in this Regulation.

2.2. Management and control system(s)

2.2.1. Justification of the budget implementation method(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed

The management mode for the initiative is direct management by the Commission. This is the most appropriate approach given the limited scope of Union expenditure, which is confined to standard administrative and monitoring-related costs. Using established internal procedures ensures effective and efficient controls, low error rates, fast processing of transactions and minimal control costs

2.2.2. Information concerning the risks identified and the internal control system(s) set up to mitigate them

Overall, the initiative requires staff expenditure. Standard rules for this type of expenditure apply. Most aspects of the initiative follow established procedures for monitoring the implementation of this Regulation. The main operational risk is insufficient administrative capacity to monitor the implementation of the obligations laid down in the Regulation. This proposal is accompanied by an impact assessment report, which provides the analytics underpinning the chosen policy approach. The preparation of the initiative also drew on a public consultation as well as targeted consultations with industry stakeholders, Member States and trade associations, which ensured the collection of relevant data, information and feedback. Nonetheless, unintentional consequences or unforeseen impacts may still occur during implementation. These will be identified through the monitoring procedures set out in the Regulation, allowing the Commission to address them in an appropriate and timely manner.

2.2.3. Estimation and justification of the cost-effectiveness of the controls (ratio between the control costs and the value of the related funds managed), and assessment of the expected levels of risk of error (at payment & at closure)

The initiative involves limited administrative expenditure. Standard Commission control procedures apply. As no funding programmes or multi-layered delivery mechanisms are created, control activities remain straightforward and cost-effective. Controls are carried out entirely under direct management, using standard ex-post audits under the Commission's internal control framework. This ensures an appropriate balance between control effort and the limited value of funds managed. Given the simplified set-up and the absence of high-risk financial operations, the expected error rate at payment and at closure is low and comfortably below the materiality threshold. The control system therefore provides a high level of assurance at proportionate cost.

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2.3. Measures to prevent fraud and irregularities

The initiative does not establish funding programmes or financial support schemes. It therefore relies on the Commission's existing internal control framework and Anti-Fraud Strategy. Standard preventive and detective measures apply, including risk-based internal controls, segregation of duties and established workflows for administrative expenditure.

The Office shall ensure, in accordance with Regulation (EU) 2017/1001 and the financial rules applicable to the Office, that appropriate measures are in place to protect the financial interests of the Union in the performance of the tasks entrusted to it under this Regulation, including measures to prevent, detect and address fraud, corruption, conflicts of interest and other irregularities. The Commission shall exercise the oversight and monitoring functions conferred on it under the applicable governance framework.

As with all Commission-managed activities, the European Anti-Fraud Office (OLAF) and the European Public Prosecutor's Office (EPPO) may exercise their powers in accordance with their respective legal bases to investigate fraud, corruption or other illegal activities affecting the EU's financial interests. The European Court of Auditors retains its standard audit rights over Commission expenditure.

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3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

The estimated impact on expenditure and staffing for 2028 and beyond is added for illustrative purposes only and does not pre-judge the next Multiannual Financial Framework. The source of financing and scope of Union financial commitment in the post-2027 period remain subject to the outcome of interinstitutional negotiations on the MFF 2028-2034 and thereafter shall be determined through the annual budgetary procedure. All appropriations and staffing allocations as of 2028 are indicative. As regards the EUIPO budget, the figures are indicative and subject to approval by the EUIPO governing bodies in accordance with the EUTMR.

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff.[32]	from EFTA countries [33]	from candidate countries and potential candidates [34]	From other third countries	other assigned revenue
02	01 01 01 01	Non-diff.	YES	YES	NO	NO

- New budget lines requested

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff.	from EFTA countries	from candidate countries and potential candidates	from other third countries	other assigned revenue
	N/A					

[32] Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.
[33] EFTA: European Free Trade Association.
[34] Candidate countries and, where applicable, potential candidates from the Western Balkans.

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3.2. Estimated financial impact of the proposal on appropriations

3.2.1. Summary of estimated impact on operational appropriations

– ☒ The proposal/initiative does not require the use of operational appropriations

– ☐ The proposal/initiative requires the use of operational appropriations, as explained below

3.2.1.1. Appropriations from voted budget

EUR million (to three decimal places)

Heading of multiannual financial framework	Number	02

DG: RTD			Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	**TOTAL MFF 2028-2034**
Operational appropriations										
Budget line	Commitments	(1a)								**0**
	Payments	(2a)								**0**
Budget line	Commitments	(1b)								**0**
	Payments	(2b)								**0**
Appropriations of an administrative nature financed from the envelope of specific programmes[35]										
Budget line 01 01 01 01		(3)	**0.582**	**0.582**	**0.582**	**0.582**	**0.582**	**0.582**	**0.582**	**4.074**
TOTAL appropriations for DG RTD	Commitments	=1a+1b+3	**0.582**	**0.582**	**0.582**	**0.582**	**0.582**	**0.582**	**0.582**	**4.074**
	Payments	=2a+2b+3	**0.582**	**0.582**	**0.582**	**0.582**	**0.582**	**0.582**	**0.582**	**4.074**

[35] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

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EUR million (to three decimal places)

		Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL MFF 2028-2034
TOTAL appropriations under HEADINGS 1 to 4	Commitments	**0.582**	**0.582**	**0.582**	**0.582**	**0.582**	**0.582**	**0.582**	**4.074**
of the multiannual financial framework	Payments	**0.582**	**0.582**	**0.582**	**0.582**	**0.582**	**0.582**	**0.582**	**4.074**

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3.2.3. *Summary of estimated impact on administrative appropriations*

– ☐ The proposal/initiative does not require the use of appropriations of an administrative nature

– ☒ The proposal/initiative requires the use of appropriations of an administrative nature, as explained below

3.2.3.1. Appropriations from voted budget

VOTED APPROPRIATIONS	Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL 2028 - 2034
HEADING 4								
Human resources	0.000	0.000	0.000	0.000	0.000	0.000	0.000	**0.000**
Other administrative expenditure	0.000	0.000	0.000	0.000	0.000	0.000	0.000	**0.000**
Subtotal HEADING 4	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
Outside HEADING 4								
Human resources	0.582	0.582	0.582	0.582	0.582	0.582	0.582	**4.074**
Other expenditure of an administrative nature	0	0	0	0	0	0	0	**0**
Subtotal outside HEADING 4	0.582	0.582	0.582	0.582	0.582	0.582	0.582	**4.074**
TOTAL	0.582	0.582	0.582	0.582	0.582	0.582	0.582	**4.074**

The estimated impact on expenditure and staffing for 2028 and beyond is added for illustrative purposes only and does not pre-judge the next Multiannual Financial Framework. The source of financing and scope of Union financial commitment in the post-2027 period remain subject to the outcome of interinstitutional negotiations on the MFF 2028-2034 and thereafter shall be determined through the annual budgetary procedure. All appropriations and staffing allocations as of 2028 are indicative.

3.2.4. *Estimated requirements of human resources*

– ☐ The proposal/initiative does not require the use of human resources

– ☒ The proposal/initiative requires the use of human resources, as explained below

3.2.4.1. Financed from voted budget

Estimate to be expressed in full-time equivalent units (FTEs)[36]

VOTED APPROPRIATIONS	Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034
• Establishment plan posts (officials and temporary staff)							
20 01 02 01 (Headquarters and Commission's Representation Offices)	0	0	0	0	0	0	0
20 01 02 03 (EU Delegations)	0	0	0	0	0	0	0
(Indirect research)	3	3	3	3	3	3	3
(Direct research)	0	0	0	0	0	0	0

[36] Please specify below the table how many FTEs within the number indicated are already assigned to the management of the action and/or can be redeployed within your DG and what are your net needs.

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Other budget lines (specify)		0	0	0	0	0	0	0
• External staff (in FTEs)								
20 02 01 (AC, END from the 'global envelope')		0	0	0	0	0	0	0
20 02 03 (AC, AL, END and JPD in the EU Delegations)		0	0	0	0	0	0	0
Admin. Support line	• at Headquarters	0	0	0	0	0	0	0
[XX.01.YY.YY]	• in EU Delegations	0	0	0	0	0	0	0
(AC, END - Indirect research)		0	0	0	0	0	0	0
(AC, END - Direct research)		0	0	0	0	0	0	0
Other budget lines (specify) - Heading 4		0	0	0	0	0	0	0
Other budget lines (specify) - Outside Heading 4		0	0	0	0	0	0	0
TOTAL		**0**	**0**	**0**	**0**	**0**	**0**	**0**

The staff required to implement the proposal (in FTEs):

	To be covered by current staff available in the Commission services	**Exceptional additional staff***		
		To be financed under Heading 4 or Research	**To be financed from BA line**	**To be financed from fees**
Establishment plan posts	3 [N.B. Considering the overall strained situation in Heading 4, in terms of both staffing and the level of appropriations, the human resources required will be met by staff from the DG who are already assigned to the management of the action and/or have been redeployed within the DG or other Commission services]		N/A	
External staff (CA, SNEs, INT)				

Description of tasks to be carried out by:

Officials and temporary staff	3 FTEs are needed to monitor the implementation and enforcement of the Regulation.

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External staff	

3.2.5. Overview of estimated impact on digital technology-related investments

Compulsory: the best estimate of the digital technology-related investments entailed by the proposal/initiative should be included in the table below.

Exceptionally, when required for the implementation of the proposal/initiative, the appropriations under Heading 4 should be presented in the designated line.

The appropriations under Headings 1-3 should be reflected as "Policy IT expenditure on operational programmes". This expenditure refers to the operational budget to be used to re-use/ buy/ develop IT platforms/ tools directly linked to the implementation of the initiative and their associated investments (e.g. licences, studies, data storage etc). The information provided in this table should be consistent with details presented under Section 4 "Digital dimensions".

TOTAL Digital and IT appropriations	Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	**TOTAL MFF 2028 - 2034**
HEADING 4								
IT expenditure (corporate)	0	0	0	0	0	0	0	**0**
Subtotal HEADING 4	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Outside HEADING 4								
Policy IT expenditure on operational programmes	0	0	0	0	0	0	0	**0**
Subtotal outside HEADING 4	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
TOTAL	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

3.2.6. Compatibility with the current multiannual financial framework

The proposal/initiative:

– ☒ can be fully financed through redeployment within the relevant heading of the multiannual financial framework (MFF)

– ☐ requires use of the unallocated margin under the relevant heading of the MFF and/or use of the special instruments as defined in the MFF Regulation

– ☐ requires a revision of the MFF

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3.2.7. Third-party contributions

The proposal/initiative:

– ☒ does not provide for co-financing by third parties

– ☐ provides for the co-financing by third parties estimated below:

Appropriations in EUR million (to three decimal places)

	Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	Total
Specify the co-financing body								
TOTAL appropriations co-financed								

3.2.8. Estimated human resources and the use of appropriations required in a decentralised agency

The Competence Centre would provide support in areas such as IP exploitation, commercialisation and access to finance. The implementation of these activities is estimated to require 10 FTEs per year during the implementation phase, assuming a two-year development period. If the Act enters into force in 2028, this phase would therefore cover 2028 and 2029. Once the Competence Centre becomes fully operational, the estimated staffing requirement would decrease to 8 FTEs per year.

Staff requirements (full-time equivalent units)

Agency: EUIPO	Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034
Temporary agents (AD Grades)	10	10	8	8	8	8	8
Temporary agents (AST grades)	0	0	0	0	0	0	0
Temporary agents (AD+AST) subtotal	10	10	8	8	8	8	8
Contract agents	0	0	0	0	0	0	0
Seconded national experts	0	0	0	0	0	0	0

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Contract agents and seconded national experts subtotal	0	0	0	0	0	0	0
TOTAL staff	10	10	8	8	8	8	8

Overview/summary of human resources and appropriations (in EUR million) required by the proposal/initiative in a decentralised agency

Agency: EUIPO	Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL 2028 - 2034
Temporary agents (AD+AST)	10	10	8	8	8	8	8	60
Contract agents	0	0	0	0	0	0	0	-
Seconded national experts	0	0	0	0	0	0	0	-
Total staff	0	0	0	0	0	0	0	-
Appropriations covered by the EU budget	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Appropriations covered by fees (if applicable)	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Appropriations co-financed (if applicable)	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
TOTAL appropriations	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000

The Office reserves its position as regards the calculation of the revenue derivable from the relevant EIA provision.

3.3. Estimated impact on revenue

– ☒ The proposal/initiative has no financial impact on revenue.

– ☐ The proposal/initiative has the following financial impact:

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– ☐ on own resources

– ☐ on other revenue

– ☐ please indicate, if the revenue is assigned to expenditure lines

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative[37]						
		Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**
Article …….								

For assigned revenue, specify the budget expenditure line(s) affected.

[…]

Other remarks (e.g. method/formula used for calculating the impact on revenue or any other information).

[…]

4. DIGITAL DIMENSIONS

4.1. Requirements of digital relevance

Reference to the requirement	Requirement description	Actor(s) affected or concerned by the requirement	High-level Processes	Categories
Article 4(4)	R&D procurements to be carried out through the TED platform (digital interface to upload procurement notices in the *Official Journal of the European Union*)	Public buyers Economic operators	R&D procurement	Data Digital Solution Digital Public Service Process digitalisation and automation Interoperability
Articles 4(4)	Requirement to use electronic format for	Public buyers Economic	R&D procurement	Data Digital Solution

[37] In the case of traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 10 % for collection costs, as proposed in COM(2025)574.

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	procurement documents	operators		Digital Public Service Process digitalisation and automation Interoperability
Article 10	Requirement on public buyers to specify requirements on contractors to contribute to publication of results, where appropriate, as open data or open source	Public buyers Economic operators	R&D procurement	Data Digital Solution Digital Public Service Process digitalisation and automation
Article 26	Requirement to respect data protection rules, including those for electronic communication	Public buyers Economic operators	R&D procurement	Data Digital Solution Digital Public Service Process digitalisation and automation
Article 32(3)(a)	European Union Intellectual Property Office to develop a valuation framework for valuation of intangible assets and related digital processes and services related to the disclosure, screening and valuation of IP	Economic operators Member States Union entities	IP valuation	Data Digital Solution Digital Public Service Process digitalisation and automation
Article 32(3)(b)	European Union Intellectual Property Office	Union entities Economic operators	Facilitation of IP licensing and transfer	Data Digital Solution Digital Public

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	to establish and maintain a digital match-making platform to facilitate the licensing and transfer of all types of IP rights protected at Union level.			Service
Article 32(3)(g) and Article 35	Development of an evidence database on IP-backed financing	Member States Competent authorities Economic operators Union entities	Data processing and analysis	Data

4.2. Data

Type of data	Reference to requirement(s)	Standard and/or specification (if applicable)
Data related to R&D procurement procedures on the scope of the procurement, on public buyers and on tenderers/contractors	Articles 4(4), 6, 16 and 17	Standards and specifications used in the EU public procurment portal (eForms, OASIS UBL, TED APIs, eProcurement ontology)
Data related to IP-backed financing, including information on how intellectual property used as collateral for credit or insurance purposes or as in-kind contribution in equity investment scenarios has been evaluated, on the size and characteristics of the corresponding transaction, on the type of intellectual property right concerned, and on relevant indicators such as equity valuation, collateralisation, or loan to value ratios.	Article 32(3)g) and Article 33	Standards and specifications to be defined by the European Union Intellectual Property Office Competence Centre for IP-backed finance, in cooperation with the Commission, covering: harmonised data requirements for IP asset type, collateral structure, transaction size, and loan outcomes; data sharing and access protocols consistent with applicable data protection rules; interoperability requirements enabling linkage between IP registries, commercial registries, and public instrument records; and standards for the anonymisation and aggregation of transaction-

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		level data collected through EU-supported IP-backed finance instruments.

Alignment with the European Data Strategy

Explain how the requirement(s) are aligned with the European Data Strategy

- The proposal promotes the use of digital tools for R&D procurement procedures and for valuation and commercialisation of IP, which is in line with the European Data Strategy's objective of promoting digitalization and data-driven innovation.
- The proposal builds on the existing digital tools for public procurement, including the national procurement portals. This is consistent with the European Data Strategy's goal of improving data sharing and interoperability.
- The proposal promotes transparency while respecting data protection and data confidentiality rules, the protection of intellectual property rights and the safeguarding of trade secrets. This is in line with the European Data Strategy's objective of promoting transparency and trust in data-driven ecosystems.
- The proposal aims to create a favorable environment for startups and scaleups, which is consistent with the European Data Strategy's goal of promoting innovation and entrepreneurship through data-driven technologies.

Explanation of how newly created data is findable, accessible, interoperable and reusable, and meets high-quality standards

The accessibility, findability, interoperability and reusability of data and the data-quality requirements related to **R&D procurements** is currently defined in the rules for publication of and access to data on the TED portal

Data collected under the Act will be managed by European Union Intellectual Property Office. The **European Union Intellectual Property Office Competence Centre** will maintain a structured repository with defined metadata standards to support discoverability and reuse. The Office is the legal entity that will maintain the repository. Access will be governed by clear protocols, distinguishing between publicly available data and data accessible only to authorised bodies. Interoperability with existing IP registries and commercial registers will be pursued through common data formats and shared identifiers. Data quality standards, including validation rules and reporting obligations for participating entities, will be defined by the Competence Centre in cooperation with the Commission.

Data flows

High-level description of the data flows

Type of data	Reference(s) to the requirement(s)	Actor who provides the data	Actor who receives the data	Trigger for the data exchange	Frequency (if applicable)
Procurement documents and notices	Articles 4(4), 6, 16 and 17	Public buyer	Tenderers	Publication of notices and link to procurement	

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				documents	
IP valuation tools	Article 32(3)(a)	EUIPO	Economic operators Public bodies	IP valuation request	
IP matchmaking information	Article 32(3)(b)	EUIPO	Economic operators Public bodies	Matchmaking request	
IP-based finance related evidence	Article 32(3)(g)	National guarantee institutions Financial intermediaries	EUIPO	Request for collection of evidence	

4.3. Digital solutions

Under this proposal, **R&D procurements** will be carried out through the digital solutions used in the TED portal.

Under this proposal, European Union Intellectual Property Office is tasked with developing the following digital solutions:

- digital tools supporting the disclosure, screening and indicative valuation of IP assets, accessible to economic operators and financial institutions
- an IP licensing and transfer platform facilitating the licensing and transfer of IP rights protected at Union level
- IP-backed finance evidence database collecting transaction-level data on IP-backed finance instruments

All three solutions will be operated by European Union Intellectual Property Office and will comply with applicable cybersecurity requirements and relevant Union digital rules. Where AI-assisted tools are used, in particular for screening and indicative valuation, compliance with rules applicable to use of AI will be ensured and the relevant risk classification will be assessed at design stage.

4.4. Interoperability assessment

The digital solutions mandated by the Act require interaction across Member State borders and involve multiple EU entities and public sector bodies, satisfying both conditions for an interoperability assessment.

Currently the TED portal provides an interoperable way for public buyers to upload R&D procurements notices that were published on national public procurement portals also on the TED portal. In the future, the EU digital market place for public procurements is expected to further improve interoperability between different national and EU public procurement portals and databases, enabling economic operators from one Member State to participate more easily in a R&D procurement procedure of a public buyer in another

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Member State, and simplifying the process for public buyers from two or more Member States to carry out R&D procurement procedures jointly. The TED portal will remain the interface for public buyers to launch R&D procurement procedures and for economic operators to find R&D procurement business opportunities. Therefore, the interactions between national and EU public procurement portals and databases are not part of this interoperability assessment.

The European Union Intellectual Property Office valuation tools and matchmaking platform will be accessible to economic operators and public bodies across all Member States, requiring semantic interoperability with national IP registries and commercial registers. The IP-backed finance evidence database will aggregate data from national guarantee institutions and financial intermediaries, requiring harmonised data formats and shared identifiers. Relevant interoperability solutions available at EU level will be assessed for reuse during the design and implementation phase. Key remaining barriers include divergent national IP registry formats and the absence of a central EU-level IP pledge register.

Since this proposal introduces new binding requirements for cross-border digital public services within the meaning of Regulation (EU) 2024/903 of the European Parliament and of the Council[38], an interoperability assessment has been carried out, and the resulting report is to be published on the Interoperable Europe Portal.

4.5. Measures to support digital implementation

The following implementation measures are planned to support the implementation of the digital solutions under this proposal:

For R&D procurement:

- the use of existing features for launching R&D procurement procedures through the TED portal, and the integration of new digital features for launching R&D procurement procedures through the EU digital market place for public procurements
- capacity building activities targeting Member States, public buyers and economic operators to support wide and correct use of launching R&D procurements through the TED portal

For the European Union Intellectual Property Office activities:

- the establishment and operationalisation of the European Union Intellectual Property Office Competence Centre for IP-backed finance, responsible for the digital tools, the matchmaking platform, and the evidence database.
- capacity building programme targeting financial institutions, developed jointly by European Union Intellectual Property Office and the Commission, to support uptake of the valuation framework and digital tools.
- pilot phase for the evidence database involving selected national guarantee institutions and financial intermediaries, enabling iterative refinement before full

[38] Regulation (EU) 2024/903 of the European Parliament and of the Council of 13 March 2024 laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act) (OJ L, 2024/903, 22.03.2024, ELI: http://data.europa.eu/eli/reg/2024/903/oj).

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