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From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

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To: Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

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Delegations will find attached document C(2024) 3148 final.

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Brussels, 8.5.2024  
C(2024) 3148 final

## COMMUNICATION FROM THE COMMISSION

**Guidance Note concerning certain provisions of Regulation (EU) 2024/795 establishing  
the Strategic Technologies for Europe Platform (STEP)**

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## COMMUNICATION FROM THE COMMISSION

### Guidance Note concerning certain provisions of Regulation (EU) 2024/795 establishing the Strategic Technologies for Europe Platform (STEP)

*The purpose of this non-binding Guidance Note issued by the European Commission is to offer practical guidance on certain provisions of the STEP Regulation, to facilitate its implementation. While the Guidance Note occasionally paraphrases the provisions of Union legislation, it is not meant to add to or diminish the rights and obligations set out in the STEP Regulation. To assess the eligibility of projects to a specific funding opportunity pursuant to the STEP Regulation, project promoters are invited to refer to the relevant programme's rules (e.g., as defined in the respective basic acts, annual work programmes, calls, and topic descriptions). Those rules continue to apply since STEP is not a new funding instrument but works through existing Union programmes. The Commission may revise or expand this Guidance Note, including in light of the interim evaluation report to be submitted to the European Parliament and the Council by 31 December 2025. This guidance is without prejudice to State aid rules<sup>1</sup>.*

#### 1. INTRODUCTION

On 1 March 2024, the Regulation (EU) 2024/795 of the European Parliament and of the Council of 29 February 2024, establishing the Strategic Technologies for Europe Platform (STEP)<sup>2</sup> (hereinafter the “STEP Regulation) entered into force. The aim of STEP is to support the development and manufacturing of critical technologies in three sectors (e.g., digital and deep technology innovation, clean and resource efficient technologies, and biotechnologies) relevant to the green and digital transitions. STEP will also support investments aimed at strengthening industrial development and reinforcing value chains, thereby reducing the Union’s strategic dependencies, strengthening Union sovereignty and economic security, and addressing labour and skills shortages in those strategic sectors. This will enhance the long-term competitiveness of the Union and strengthen its resilience.

Eleven Union programmes and funds are relevant to the implementation of STEP: the Digital Europe Programme, the European Defence Fund, EU4Health, Horizon Europe, the Innovation Fund, InvestEU, the Recovery and Resilience Facility, as well as the Cohesion Fund, the European Regional Development Fund, the European Social Fund Plus (ESF+), and the Just Transition Fund.

The Guidance Note is structured as follows:

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<sup>1</sup> For measures constituting State aid pursuant to Article 107(1) TFEU, Member States must ensure compliance with the compatibility conditions of the applicable State aid rules.

<sup>2</sup> OJ L, 2024/795, 29.2.2024, ELI: <http://data.europa.eu/eli/reg/2024/795/oj>

- Section 1 focuses on the two main objectives underlying the STEP Regulation in line with Article 2(1) of the STEP Regulation.
- Section 2 clarifies the three technological areas supported by STEP, providing examples of the technological sectors falling within the scope of STEP in line with Article 2(1)(a) of the STEP Regulation.
- Section 3 illustrates the conditions for a technological sector to be considered critical, in line with Article 2(2) of the STEP Regulation.

## 1. STEP OBJECTIVES

Article 2(1) of the STEP Regulation sets out STEP's main objectives: (a) supporting the development or manufacturing of critical technologies throughout the Union or safeguarding and strengthening their respective value chains; and (b) addressing shortages of labour and skills critical to all kinds of quality jobs in support of the first objective. These objectives are further elaborated below.

### 1.1. Supporting the development or manufacturing of critical technologies throughout the Union, or safeguarding and strengthening their respective value chains

#### 1.1.1 Supporting the development or manufacturing of critical technologies throughout the Union

In the context of the STEP Regulation, development and manufacturing pertain to advancing technologies from the stage where feasibility was demonstrated through to commercial production. This includes refining prototypes, and/or ensuring that technologies meet rigorous standards for performance and scalability. Development encompasses activities aimed at achieving technological breakthroughs, perfecting the technology for market needs, including enhancing its efficiency, reliability, and developing standards.

The development and manufacturing of critical technologies in the Union is dependent on advanced European or international standards to ensure the quality, reliability and interoperability of technological solutions, products, and services across the internal market and for global competitiveness. They are also a critical indicator for the maturity and market readiness of technologies, being a positive factor for attracting investments.

Manufacturing includes setting up production lines, first-of-a-kind-facilities<sup>3</sup>, the extension or repurposing of existing facilities, scaling up processes to meet demand, and/or implementing

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<sup>3</sup> For net-zero technologies, Article 3 of the Net-Zero Industry Act (NZIA) defines 'first-of-a-kind' as "a new or substantially upgraded net zero technology facility which provides innovation with regard to the manufacturing process of the net-zero technology that is not yet substantively present or committed to be built within the Union".

quality control mechanisms to ensure the consistent production of high-quality products. This approach ensures that innovations are not only technologically advanced but also economically viable and ready for widespread adoption across the Union, reinforcing the Union's strategic autonomy and competitiveness in key technological areas. STEP does not include the installation and deployment of the final products, but it does cover associated services that are critical and specific to the development and manufacturing of these products within the STEP sectors (see section 1.1.2 below).

To qualify as critical, technologies should be required either to bring to the internal market an innovative, emerging, and cutting-edge element with significant economic potential, or to contribute to reducing or preventing the strategic dependencies of the Union (see section 3 below).

### **1.1.2 *Safeguarding and strengthening value chains***

The STEP Regulation highlights the vital importance of strengthening the entire value chain associated with the development or manufacturing of critical technologies to reduce the Union's strategic dependencies and preserving the integrity of the internal market.

In this context, pursuant to Article 2(3) of the STEP Regulation, the term 'value chain' relates to: final products; specific components and specific machinery primarily used to produce the final products; critical raw materials set out in an Annex II to the Critical Raw Materials Act (CRMA)<sup>4</sup>; associated services critical for and specific to the development or manufacturing of those final products; and technologies that fall under the scope of the Net-Zero Industry Act (NZIA)<sup>5</sup>.

**Specific components and specific machinery** are intended as parts and equipment primarily used for the development and manufacturing of critical technologies. They have the potential to enhance technological innovation and production efficiency in the relevant critical technology sectors (digital and deep tech innovation, clean and resource efficient, and bio tech). For example, in the digital technology sector, advanced computing components — such as quantum processors — represent a fundamental link in the value chain. Their development requires highly specialised equipment and expertise.

**Critical raw materials**, as defined in Annex II of the CRMA, are important to produce critical technologies under STEP. For example, silicon is crucial to produce semiconductors, and rare earths, for robotics. Likewise, lithium, nickel and cobalt are essential for batteries, platinum for electrolyzers, and copper for the electric grid. In addition, a lot of the equipment and tools used in biotechnology research relies on critical raw materials, for example rare earths for the

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<sup>4</sup> Regulation of the European Parliament and of the Council on establishing a framework for ensuring a secure and sustainable supply of critical raw materials (Critical Raw Materials Act), politically agreed on 13 November 2023, not yet published.

<sup>5</sup> Regulation of the European Parliament and of the Council on establishing a framework of measures for strengthening Europe's net-zero technology products manufacturing ecosystem (Net-Zero Industry Act), politically agreed on 6 February 2024, not yet published.

permanent magnets in magnetic resonance imaging devices, and platinum or titanium in implantable medical devices. The focus on these critical raw materials within the value chain is essential for ensuring that the Union's transition to a green economy and the competitiveness of its industry is not hindered by supply vulnerabilities.

**Associated services**, pursuant to Article 2(3) of the STEP Regulation, include specialised services that are critical for and specific to the development and manufacturing of the final products within the scope of STEP. Associated services falling within the scope of STEP are considered to be those that are both critical for and specific to the relevant critical technology (be it digital/deep tech innovation, clean and resource efficient, and/or bio technologies), in that for example they enhance its content and efficiency.

Examples of associated services include cleanroom services for the manufacturing of semiconductors, cloud/edge computing services, high performance computing services, testing and experimentation services, cybersecurity services, space-based IoT and secure connectivity services specific to smart manufacturing, space-based positioning, navigation, and timing (PNT), services for real-time monitoring and tracking and specialised clinical trial management to develop new pharmaceutical products. Such associated services are eligible to receive funding under the scope of STEP as standalone projects.

Ancillary services such as IT, advisory or legal activities, may only be supported via STEP if they are an inherent part of the investment cost of a STEP project, provided this is in line with the rules applicable to the Union instrument or Fund concerned. These services on their own do not qualify as a STEP project.

## 1.2. Addressing shortages of labour and skills

The STEP Regulation recognises that the Union's ambitions to lead in the development and manufacturing of critical technologies hinge on overcoming significant labour and skills shortages. These shortages are particularly acute in some areas pivotal to the green and digital transition, a challenge that is set to intensify with demographic shifts. Addressing this gap is crucial for ensuring the success of technologies in the STEP sectors.

By facilitating investments in sector-specific training, life-long learning and education, the Regulation aims to ensure that the workforce is equipped with the specialised knowledge and skills essential for advancing the Union's capabilities in digital innovation, clean and resource-efficient technologies, and biotechnology. This approach to skills development is designed to directly support the growth and competitiveness of the Union's strategic sectors, with a particular emphasis on creating opportunities for young and disadvantaged individuals who are currently outside the employment, education, or training systems, also with a view to realising the full potential of the green and digital transitions in a socially fair, inclusive, and just manner. The STEP Regulation is complementary to the broader European Skills Agenda<sup>6</sup> and other skills specific sector initiatives, focusing specifically on closing the skills gap in areas critical for the success of the STEP sectors. STEP projects are encouraged to build on existing projects and

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<sup>6</sup> <https://ec.europa.eu/social/main.jsp?catId=1223&langId=en>

initiatives linked to the sectors to be addressed, such as those developed by the EU Pact for Skills, or by the European Skills Agenda Centres of Vocational Excellence<sup>7</sup>.

Therefore, the STEP Regulation targets the skill sets relevant to the development and manufacturing of critical technologies across the STEP sectors, while creating quality jobs and apprenticeships. Broader and transferable skills could be considered in accordance with fund-specific rules.

For example, in the realm of clean and resource efficient technology, STEP seeks to support skills projects in advanced battery technology and renewable energy system maintenance, in addition to other relevant engineering skills. For digital tech, developing cybersecurity and data analytics skills would be relevant under STEP.

The STEP Regulation highlights the crucial role of European Net-Zero Industry Academies, established under the NZIA. Pursuant to Article 12 of the STEP Regulation, Member States may use their ESF+ resources for skills development in net-zero technologies.

## 2. STEP TECHNOLOGY SECTORS

Pursuant to Article 2(1), point (a) of the STEP Regulation, the following sectors are considered to be in the scope of STEP:

- **Digital technologies**, including those contributing to the targets and objectives of the Digital Decade Policy Programme 2030, multi-country projects as defined in Article 2(2) of Decision (EU) 2022/2481, and **deep tech innovation**;
- **Clean and resource efficient technologies**, including net-zero technologies as defined under the Net-Zero Industry Act; and
- **Biotechnologies**, including medicinal products on the Union list of critical medicines<sup>8</sup> and their components.

The criticality condition in Article 2(2) of the STEP Regulation sets out criticality as a qualitative criterion, which means that the remit of the STEP Regulation is not fixed but may evolve in accordance with technological changes and/or geopolitical and international trade developments and that this Guidance Note does not preclude future evolutions of the scope. Furthermore, ongoing and/or future assessments or evaluations carried out by the Commission may complement this Guidance Note. Important references include the Versailles Declaration<sup>9</sup>

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<sup>7</sup> Erasmus+ Centres of Vocational Excellence projects focus in areas linked to the digital and green transition such as AI, cloud computing, micro-electronics, advance manufacturing, or sustainable energy. More information is available at <https://ec.europa.eu/social/main.jsp?catId=1501>

<sup>8</sup> <https://www.ema.europa.eu/en/news/first-version-union-list-critical-medicines-agreed-help-avoid-potential-shortages-eu>

<sup>9</sup> <https://www.consilium.europa.eu/en/press/press-releases/2022/03/11/the-versailles-declaration-10-11-03-2022/>

(2022), the Net-Zero Industry Act<sup>10</sup>, the Critical Raw Material Act<sup>11</sup>, the Communication on long-term competitiveness of the European Union<sup>12</sup> (2023), or the European Innovation Agenda (2022)<sup>13</sup>, the Digital Decade Policy Programme<sup>14</sup> (2022) and the Communication from the Commission on boosting biotechnology and biomanufacturing in the EU<sup>15</sup> (2024).

The scope of STEP is aligned with the Commission recommendation of 3.10.2023 on critical technology areas relevant for the Union's economic security or further risk assessment with Member States<sup>16</sup>. A list containing ten critical technology areas has been established in the Annex to the Commission Recommendation following an assessment of the enabling and transformative nature of the technology, the risk of civil and military fusion, and the risk of misuse of the technology for human rights violations.

The sections below provide, for each STEP sector, an indicative and non-exhaustive list of examples and relevant definitions of technologies that could be considered in the scope of the STEP sectors, including on the basis of the above-listed texts.

## 2.1 Digital technologies and deep tech innovation

### 2.1.1 Digital technologies

The Digital Decade Policy Programme 2030<sup>17</sup> establishes digital targets and objectives in the realms of digital skills, digital infrastructure, and digitalisation of business and of public services. It mentions several digital technologies contributing to the targets and objectives, including, but not limited to, artificial intelligence, 5G, 6G, blockchain, high performance computing, cloud and edge computing, and the internet of things.

The Commission's Recommendation on critical technology areas for the Union's economic security<sup>18</sup> sets out in its Annex an indicative and non-exhaustive list of critical technology areas<sup>19</sup>

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<sup>10</sup> Regulation of the European Parliament and of the Council on establishing a framework of measures for strengthening Europe's net-zero technology products manufacturing ecosystem (Net-Zero Industry Act), politically agreed on 6 February 2024, awaiting official publication.

<sup>11</sup> Regulation of the European Parliament and of the Council on establishing a framework for ensuring a secure and sustainable supply of critical raw materials (Critical Raw Materials Act), politically agreed on 13 November 2023, awaiting official publication.

<sup>12</sup> [https://commission.europa.eu/system/files/2023-03/Communication\\_Long-term-competitiveness.pdf](https://commission.europa.eu/system/files/2023-03/Communication_Long-term-competitiveness.pdf)

<sup>13</sup> [https://research-and-innovation.ec.europa.eu/strategy/support-policy-making/shaping-eu-research-and-innovation-policy/new-european-innovation-agenda\\_en](https://research-and-innovation.ec.europa.eu/strategy/support-policy-making/shaping-eu-research-and-innovation-policy/new-european-innovation-agenda_en)

<sup>14</sup> [https://commission.europa.eu/europes-digital-decade-digital-targets-2030-documents\\_en](https://commission.europa.eu/europes-digital-decade-digital-targets-2030-documents_en)

<sup>15</sup> [https://research-and-innovation.ec.europa.eu/document/download/47554adc-dffc-411b-8cd6-b52417514cb3\\_en](https://research-and-innovation.ec.europa.eu/document/download/47554adc-dffc-411b-8cd6-b52417514cb3_en)

<sup>16</sup> [https://defence-industry-space.ec.europa.eu/commission-recommendation-03-october-2023-critical-technology-areas-eus-economic-security-further\\_en](https://defence-industry-space.ec.europa.eu/commission-recommendation-03-october-2023-critical-technology-areas-eus-economic-security-further_en)

<sup>17</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022D2481>

<sup>18</sup> [https://defence-industry-space.ec.europa.eu/commission-recommendation-03-october-2023-critical-technology-areas-eus-economic-security-further\\_en](https://defence-industry-space.ec.europa.eu/commission-recommendation-03-october-2023-critical-technology-areas-eus-economic-security-further_en)

for further risk assessment by the Member States and the Commission. Most of the areas on the list can be considered as digital technologies relevant for STEP.

The table below constitutes an indicative and non-exhaustive list of those digital technologies mentioned in the Annex to the Commission Recommendation that are considered that are considered relevant for STEP.

Digital technology areas	Technologies (indicative, non-exhaustive)
<b>Advanced semiconductors technologies</b>	Microelectronics, including processors; photonic including high energy laser technologies; high frequency chips; semiconductor manufacturing equipment at very advanced node sizes; space-qualified semiconductor technologies
<b>Artificial intelligence technologies</b>	AI algorithms; high performance computing (HPC); cloud and edge computing; data analytics technologies; computer vision, language processing, object recognition; privacy-preserving technologies (e.g., federated learning)
<b>Quantum technologies</b>	Quantum computing; quantum cryptography; quantum communications; Quantum Key Distribution (QKD); quantum sensing including quantum gravimetry; quantum radar; quantum simulation; quantum imaging; quantum clocks; metrology; space-qualified quantum technologies
<b>Advanced connectivity, navigation, and digital technologies</b>	Secure digital communications and connectivity, such as RAN (Radio Access Network) & Open RAN (Radio Access Network), and 5G and 6G; cyber security technologies including cyber-surveillance, security and intrusion systems, digital forensics; internet of things and virtual reality; distributed ledger and digital identity technologies; guidance, navigation, and control technologies, including avionics and maritime positioning, and space-based PNT; satellite-based secure connectivity
<b>Advanced sensing technologies</b>	Electro-optical, radar, chemical, biological, radiation and distributed sensing; magnetometers, magnetic gradiometers; underwater electric field sensors; gravity meters, and gradiometers
<b>Robotics and autonomous systems</b>	Autonomous habited and uninhabited vehicles (space, air, land, surface, and underwater), including swarming; robots and robot-controlled precision systems; exoskeletons; AI-enabled systems

<sup>19</sup>

[https://defence-industry-space.ec.europa.eu/document/download/d2649f7e-44c4-49a9-a59d-bffd298f8fa7\\_en?filename=C\\_2023\\_6689\\_1\\_EN\\_annexe\\_acte\\_autonome\\_part1\\_v9.pdf](https://defence-industry-space.ec.europa.eu/document/download/d2649f7e-44c4-49a9-a59d-bffd298f8fa7_en?filename=C_2023_6689_1_EN_annexe_acte_autonome_part1_v9.pdf)

### 2.1.2 Deep tech innovation

Recital 6 of the STEP Regulation indicates that deep tech innovation should be understood as innovation with the potential to deliver transformative solutions, rooted in cutting-edge science, technology, and engineering, including innovation that combines advances in the physical, biological, and digital spheres. Deep tech innovation may be cross-cutting and found at the intersection across the digital technologies, clean and resource efficient technologies, and biotechnologies. Transformative potential may also emerge where the technologies in the three STEP sectors are combined, for example in the areas of nanobiotechnology or bioinformatics, advanced energy storage technologies, such as next-generation batteries and supercapacitors, and smart grids. Transformative potential also exists when the technologies (e.g., advanced semiconductors, quantum technologies, solar technologies, or robotics) require specific development and manufacturing methods to respond to harsh environment like space and defence, for example in the areas of space-based secure communication. Deep tech sectors, sub-sectors, applications, and definitions may change as technologies<sup>20</sup> and markets evolve over time.

## 2.2 Clean and resource efficient technologies

Pursuant to article 2(1) of the STEP Regulation, clean and resource efficient technologies include net-zero technologies as defined by the NZIA in its Article 4. In addition, at the latest by 9 months of the entry into force of the NZIA, the Commission is to adopt a delegated act to amend its Annex based on the list of net-zero technologies set out in Article 4 of the NZIA, in order to identify the sub-categories within net-zero technologies and the list of specific components used for these technologies.

The table below lists technologies covered in the NZIA Article 4 and its Annex.

Clean and resource efficient technology areas as defined under the NZIA	Clean and resource efficient technologies as defined under the NZIA
<b>Solar technologies</b>	Solar photovoltaic technologies; solar thermal electric technologies; solar thermal technologies; other solar technologies

<sup>20</sup> Examples of deep technologies can be found in the EIC Work Programme, 2024, available at [https://eic.ec.europa.eu/eic-2024-work-programme\\_en](https://eic.ec.europa.eu/eic-2024-work-programme_en); and the EIC Impact Report, 2023, available at [https://eic.ec.europa.eu/news/european-innovation-council-impact-report-2023-eu70-billion-deep-tech-portfolio-2024-03-18\\_en](https://eic.ec.europa.eu/news/european-innovation-council-impact-report-2023-eu70-billion-deep-tech-portfolio-2024-03-18_en)

<b>Onshore wind and offshore renewable technologies</b>	Onshore wind technologies; offshore renewable technologies
<b>Battery and energy storage technologies</b>	Battery technologies; energy storage technologies
<b>Heat pumps and geothermal energy technologies</b>	Heat pump technologies; geothermal energy technologies
<b>Hydrogen technologies</b>	Electrolysers; hydrogen fuel cells; other hydrogen technologies
<b>Sustainable biogas and biomethane technologies</b>	Sustainable biogas technologies; sustainable bio-methane technologies
<b>Carbon capture and storage technologies</b>	Carbon capture technologies; carbon storage technologies
<b>Electricity grid technologies</b>	Electricity grid technologies; electric charging technologies for transportation; technologies to digitalise the grid; other electricity grid technologies
<b>Nuclear fission technologies</b>	Nuclear fission energy technologies; nuclear fuel cycle technologies
<b>Sustainable alternative fuels technologies</b>	Sustainable alternative fuels technologies
<b>Hydropower technologies</b>	Hydropower technologies
<b>Other renewable energy technologies</b>	Osmotic energy technologies; ambient energy technologies, other than heat pumps; biomass technologies; landfill gas technologies; sewage treatment plant gas technologies; other renewable energy technologies
<b>Energy system-related energy efficiency technologies</b>	Energy system-related energy efficiency technologies; heat grid technologies; other energy system-related energy efficiency technologies
<b>Renewable fuels of non-biological origin technologies</b>	Renewable fuels of non-biological origin technologies
<b>Biotech climate and energy solutions</b>	Biotech climate and energy solutions

<b>Transformative industrial technologies for decarbonisation</b>	Transformative industrial technologies for decarbonisation
<b>CO<sub>2</sub> transport and utilisation technologies</b>	CO <sub>2</sub> transport technologies; CO <sub>2</sub> utilisation technologies
<b>Wind and electric propulsion technologies for transportation</b>	Wind propulsion technologies; electric propulsion technologies
<b>Other nuclear technologies</b>	Other nuclear technologies

The Commission's Recommendation on critical technology areas for the Union's economic security<sup>21</sup> provides an indication of certain critical clean and resource efficient technologies. The table below constitutes an indicative and non-exhaustive list of clean and resource efficient technologies relevant for STEP.

<b>Other clean and resource efficient technology areas</b>	<b>Other clean and resource efficient technologies (indicative, non-exhaustive)</b>
<b>Advanced materials, manufacturing and recycling technologies</b>	Technologies for nanomaterials; smart materials; advanced ceramic materials; stealth materials; safe and sustainable by design materials; additive manufacturing; digital controlled micro-precision manufacturing and small-scale laser machining/welding; technologies for extraction; processing and recycling of critical raw materials and other components (e.g. catalyst, batteries), including hydrometallurgical extraction, bioleaching, nanotechnology-based filtration, electrochemical processing and black mass
<b>Technologies vital to sustainability such as water purification and desalination</b>	Purification and desalination technologies
<b>Circular economy technologies</b>	Technologies for the reuse and recycling of electronics (e-waste); circular bioeconomy technologies (e.g., for converting waste to valuable bio-based materials or energy)

<sup>21</sup>[https://defence-industry-space.ec.europa.eu/commission-recommendation-03-october-2023-critical-technology-areas-eus-economic-security-further\\_en](https://defence-industry-space.ec.europa.eu/commission-recommendation-03-october-2023-critical-technology-areas-eus-economic-security-further_en)

## 2.3 Biotechnologies

Recital 6 of the STEP Regulation indicates that biotechnologies should be understood as the application of science and technology to living organisms, as well as parts, products, and models thereof, to alter living or non-living materials to produce knowledge, goods and services. This definition is deliberately broad to cover existing and future biotechnology activities and is in line with the single statistical definition of biotechnology developed by the OECD<sup>22</sup>. Biotechnology can also generally be defined as/by any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

Sectors of application for biotechnologies include industrial bio-based sectors (e.g., packaging materials, textiles, composites, insulation and construction materials, biofuels, paints, adhesives, solvents); environmental services (e.g., biosensors, soil/water/air decontamination); agri-food sector (e.g., biofertilizers) or pharmaceuticals and medical sectors (e.g., vaccines, organoids, gene, and cell therapy).

The table below presents an indicative and non-exhaustive list of biotechnologies relevant for STEP, based on the list-based statistical definitions of the OECD. It is supplemented by medicines that are on the Union List of Critical Medicines<sup>23</sup> and their components.

Biotechnology areas <sup>24</sup>	Biotechnologies (indicative, non-exhaustive)
<b>DNA/RNA</b>	Genomics; pharmacogenomics; gene probes; genetic engineering; DNA/RNA sequencing/synthesis/amplification; gene expression profiling, and use of antisense technology; large-scale DNA synthesis; new genomic techniques; gene drive.
<b>Proteins and other molecules</b>	Sequencing/synthesis/engineering/manufacturing of proteins and peptides (including large molecule hormones); improved delivery methods for large molecule drugs; proteomics; protein isolation and purification; signalling; identification of cell receptors; developing polyclonal products.
<b>Cell and tissue culture and engineering</b>	Cell/tissue culture; tissue engineering (including tissue scaffolds and biomedical engineering); cellular fusion; marker assisted

<sup>22</sup> [https://www.oecd-ilibrary.org/industry-and-services/revised-proposal-for-the-revision-of-the-statistical-definitions-of-biotechnology-and-nanotechnology\\_085e0151-en](https://www.oecd-ilibrary.org/industry-and-services/revised-proposal-for-the-revision-of-the-statistical-definitions-of-biotechnology-and-nanotechnology_085e0151-en)

<sup>23</sup> First version of the Union list of critical medicines agreed to help avoid potential shortages in the EU available at: <https://www.ema.europa.eu/en/news/first-version-union-list-critical-medicines-agreed-help-avoid-potential-shortages-eu>

<sup>24</sup> By extension, medicines on the Union list of Critical Medicines produced with a chemical process (and their intermediates) would be eligible as well as would reagents required to test/release the products.

	breeding technologies; metabolic engineering; cell therapies; bioprinting of cells/replacement organs
<b>Process biotechnology techniques</b>	Fermentation using bioreactors; biorefining; bioprocessing; bioleaching; biopulping; biobleaching; biodesulphurisation; bioremediation; biosensing; biofiltration and phytoremediation; molecular aquaculture; protection and decontamination including human decontaminating agents; biocatalysis, novel test techniques suitable for high throughput screening; process improvement and delivery optimisation for biopharmaceuticals and advanced therapy medicinal products
<b>Gene and RNA vectors</b>	Gene therapy; viral vectors
<b>Bioinformatics</b>	Construction of databases on genomes; protein sequences; modelling complex biological processes; including systems biology; developing personalised genomics
<b>Nanobiotechnology</b>	Application of the tools and processes of nano/microfabrication to build devices for studying biosystems and applications in drug delivery, diagnostics, manufacturing.

### 3. STEP CONDITIONS

Article 2(2) of the STEP Regulation specifies that the technologies referred to in section 2 of the Guidance Note are to be deemed critical where they meet **either** of the following conditions:

- they bring to the internal market an innovative, emerging, and cutting-edge element with significant economic potential;
- they contribute to reducing or preventing the strategic dependencies of the Union.

These two conditions are not cumulative in the assessment of criticality. They are elaborated further in the following subsections. Authorities in charge of the programmes falling within the scope of the STEP Regulation should set specific criteria to meet the above conditions in their funding processes (e.g., calls for proposals) and accordingly must assess compliance with these conditions in the evaluation of the submitted projects.

The internal market dimension for the first condition and the Union dimension for the second condition are explicit in the text of the STEP Regulation.

### **3.1 Innovative, emerging, and cutting-edge element, and significant economic potential**

STEP aims to support the development and manufacturing of critical technologies. They bring an innovative, emerging, and cutting-edge element (Article 2(2), point (a) of the STEP Regulation) with significant economic potential to the internal market.

A combination of at least two of these elements could lead to a technology being deemed as critical in the meaning of Article 2(2), point (a). Innovative elements bring in the key criterion of ‘novelty’, leading to notable improvements or changes in a particular field or industry. Emerging elements refer to new, recently developed technologies, which can, for example, arise from the research base and are starting to gain traction and show promise of significant growth or impact<sup>25</sup>. Cutting-edge elements refer to the most advanced, innovative, and sophisticated technologies currently available or in development in the Union.

STEP support should prioritise breakthrough innovations, which have the potential to be market-shaping, disrupting, or creating, and to bring significant economic potential to the Union.

The significance of the economic potential should be assessed in terms of technologies that could address a variety of Union markets (rather than geographically limited markets) or to have a substantial impact on the development or manufacturing of the technology.

STEP technologies are those which will likely carry the highest spillover effects in other Member States, which can increase the economic potential for the single market (in line with recital 5 of the STEP Regulation). Cross-border spillovers could be measured in terms of their positive contribution to growth, employment, and R&D investments.

### **3.2 Reducing or preventing strategic dependencies**

Pursuant to Article 2(2), point (b) of the STEP Regulation, technologies under the relevant STEP sectors are to be deemed critical where they contribute to reducing or preventing the strategic dependencies of the Union.

A number of dependencies and vulnerabilities have been identified in a set of assessments and roadmaps carried out at Union level<sup>26</sup>:

- i. Anticipating and monitoring the Union’s strategic dependencies has been regularly performed by the Commission as part of the Industrial Policy Update<sup>27</sup>. In 2021, the

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<sup>25</sup> In accordance with the EIC Working Paper 01/2022, 2022, available at: [https://eic.ec.europa.eu/document/download/f8784d43-c128-4338-90b7-0e67e8217dc1\\_en](https://eic.ec.europa.eu/document/download/f8784d43-c128-4338-90b7-0e67e8217dc1_en)

<sup>26</sup> The understanding of what constitutes strategic dependencies evolves in accordance with technological changes and/or geopolitical and international trade developments. Strategic dependencies may be recognised in other EU-level documents.

<sup>27</sup> Commission Communication updating the 2020 New Industrial Strategy: Building a stronger Single Market for Europe’s recovery, 2021, available at [https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age/european-industrial-strategy\\_en](https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age/european-industrial-strategy_en)

Commission has carried out eleven in-depth reviews of dependencies in different strategic areas<sup>28</sup>.

- ii. In line with its 2021 Action Plan<sup>29</sup>, the Commission established the Observatory of Critical Technologies (OCT)<sup>30</sup> to assess all technologies vital to space, defence, and civil industries, identifying supply chain weaknesses, capability gaps, and dependencies outside the Union. The OCT, which relies on comprehensive data beyond mere statistical extrapolation, is critical for monitoring the robustness of supply chains, especially in low-volume yet crucial sectors.
- iii. The European Economic Security Strategy<sup>31</sup> (2023), identified several broad and non-exhaustive categories of risks to economic security, which reflects the Union dimension of the analysis of risks which have potential effects on the entire Union. One category emphasises risks related to the resilience of supply chains, including dependencies that are more likely to be weaponised for geopolitical purposes. To mitigate these risks, the Strategy is based, among other goals, on promoting the Union's competitiveness and growth, strengthening the internal market, supporting a strong and resilient economy, and fostering the Union's research, technological and industrial base. STEP is a key tool in this respect. It aims to support the development and manufacturing in the Union of critical technologies and to strengthen their respective value chains to reduce or prevent strategic dependencies of the Union, in line with State aid rules.
- iv. Based on the EU list of critical medicines<sup>32</sup>, the Commission has performed a first vulnerability assessment on eleven medicines and will continue to implement its dedicated policy mandate in this field<sup>33</sup>.

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<sup>28</sup> Commission Staff Working Document (SWD) on strategic dependencies and capacities, 2022, available at <https://ec.europa.eu/newsroom/cipr/items/738844/en>

<sup>29</sup> Action Plan on Synergies between civil, defence and space industries, 2021, available at: [https://commission.europa.eu/system/files/2021-03/action\\_plan\\_on\\_synergies\\_en\\_1.pdf](https://commission.europa.eu/system/files/2021-03/action_plan_on_synergies_en_1.pdf)

<sup>30</sup> [https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age/stronger-european-defence\\_en](https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age/stronger-european-defence_en)

<sup>31</sup> Joint Communication on European Economic Security Strategy, 2023, available at: <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:52023JC0020>

<sup>32</sup> First version of the Union list of critical medicines agreed to help avoid potential shortages in the EU available at: <https://www.ema.europa.eu/en/news/first-version-union-list-critical-medicines-agreed-help-avoid-potential-shortages-eu>

<sup>33</sup> Further to the Commission Communication on addressing shortages of critical medicines in the EU, 2023, available at: [https://commission.europa.eu/system/files/2023-10/Communication\\_medicines\\_shortages\\_EN\\_0.pdf](https://commission.europa.eu/system/files/2023-10/Communication_medicines_shortages_EN_0.pdf)

Moreover, a strategic dependency may be deemed to exist where the European Union relies significantly on third-countries sources of supply for a technology referred to in Article 2(1), point (a).

For the purposes of the STEP Regulation, several of the following factors should be considered when determining whether technologies **reduce or prevent strategic dependencies of the Union:**

- *Contributing to Union industrial and technological leadership:* Union industrial and technological leadership in the relevant STEP sectors referred to in section 2 would give the Union a competitive edge in the global technology landscape and help prevent dependencies. For example, STEP could support the development of advanced manufacturing techniques, such as additive manufacturing, which could enhance the Union's competitive edge in high-tech industries.
- *Contributing to critical infrastructures at European level:* unrestricted access<sup>34</sup> to essential components and technologies will enable the development and manufacturing of the Union's critical infrastructures without risk of disruption or delay in supply. For example, STEP could support the development of critical technologies required in space-based and ground-based satellite systems, and electricity grids.
- *Increasing manufacturing capacity:* by increasing manufacturing capacity of critical raw materials, key components or value chains within the Union, where there is a risk of strategic dependency in the Union, some investments can directly reduce dependencies on third-country sources, thereby enhancing the Union's self-sufficiency and resilience. For example, STEP could support the creation of manufacturing facilities for critical components and/or their value chain, such as battery facilities, semiconductor chips or pharmaceuticals.
- *Strengthening security of supply:* enhancing the security of supply for critical inputs, components, and technologies in the Union presupposes a broad understanding that dependencies are to be managed collectively. A measure may address a regional security of supply issue, which in turn reinforces the Union's ability to address supply disruptions and vulnerabilities effectively in any part of its territory. For example, STEP could support the onshoring of specific critical medicines production where there is a strategic dependency in the Union or via support to critical raw materials projects.
- *Promoting positive cross-border effects in the internal market:* fostering cooperation and coordination within the internal market can help create resilient industry supply chains and downstream sectors. It also promotes a level playing field, thereby reducing distortions and enhancing overall competitiveness. For example, STEP could support the coordinated development of advanced battery storage systems for renewable energy integration, by pooling expertise and resources across Member States.

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<sup>34</sup> Free of non-EU export restrictions with extra territorial applicability.

### **3.3 Relation with the Net Zero Industry Act and the Critical Raw Materials Act**

Pursuant to Article 2(4) and (5) of the STEP Regulation, projects recognised as strategic under the NZIA or the CRMA, are automatically deemed to contribute to STEP objectives.

Pursuant to Article 2(4) of the STEP Regulation, strategic projects recognised in accordance with the relevant provision of the NZIA that comply with the criteria on resilience<sup>35</sup>, or the criteria on a positive impact on the Union's supply chain of the NZIA, or the criteria on a contribution to the Union's climate or energy objectives of the NZIA, are deemed to contribute to the STEP objective in the STEP sector relevant for clean and resource efficient technologies. Member States are to recognise as net-zero strategic projects those net-zero technology manufacturing projects located in the Union pursuant to the relevant provisions in the NZIA. At the latest by 9 months of the entry into force of the NZIA, the Commission is to adopt a delegated act to amend its Annex based on the list of net-zero technologies set out in Article 4 of the NZIA, in order to identify the sub-categories within net-zero technologies and the list of specific components used for these technologies.

Pursuant to Article 2(5) of the STEP Regulation, strategic projects recognised in accordance with the relevant provision of the CRMA are deemed to contribute to the STEP objective in the three relevant STEP sectors. Article 7 of the CRMA indicates that applications for recognition of a critical raw material project as a strategic project are to be submitted by the project promoter to the Commission.

### **3.4 Important project of common European interest (IPCEI)**

Recital 6 of the STEP Regulation indicates that technologies that fall within the three STEP sectors, which are the subject of an important project of common European interest (IPCEI)<sup>36</sup> approved by the Commission pursuant to Article 107(3), point (b), of the Treaty of the Functioning of the European Union (TFEU) should be deemed critical, and individual projects within the scope of such an IPCEI should be eligible for funding, in accordance with the rules of the relevant programmes, to the extent that the identified funding gap or, where relevant, the eligible costs, have not yet been completely covered.

The Commission keeps an updated list of approved and integrated IPCEIs<sup>37</sup>, of which several could be considered relevant for STEP considering the underlying technologies fall within the three STEP sectors, including but not limited to<sup>38</sup>:

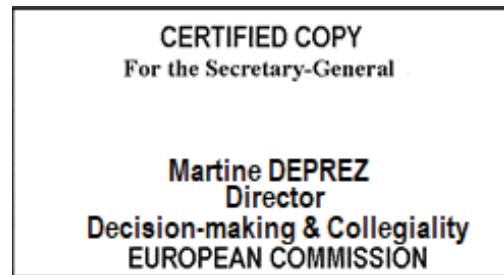
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<sup>35</sup> The selection criterion on technological and industrial resilience is fulfilled when one of the three sub-criteria listed in Article 13(1) point (a) of the NZIA is fulfilled – for instance, by adding manufacturing capacity in the Union for a net-zero technology, for which the Union depends for more than 50% on imports coming from third countries.

<sup>36</sup> [https://competition-policy.ec.europa.eu/state-aid/ipcei\\_en](https://competition-policy.ec.europa.eu/state-aid/ipcei_en)

<sup>37</sup> [https://competition-policy.ec.europa.eu/state-aid/ipcei/approved-ipceis\\_en](https://competition-policy.ec.europa.eu/state-aid/ipcei/approved-ipceis_en)

- IPCEI on the microelectronics value chain<sup>39</sup>;
- IPCEI on the batteries value chain<sup>40</sup>;
- IPCEI on the hydrogen value chain<sup>41</sup>;
- IPCEI on cloud and edge computing<sup>42</sup>.




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<sup>38</sup> There is a pending IPCEI on health, available at [https://www.economie.gouv.fr/files/files/2022/Press\\_Manifesto\\_towards\\_health\\_IPCEI.pdf](https://www.economie.gouv.fr/files/files/2022/Press_Manifesto_towards_health_IPCEI.pdf)

<sup>39</sup> [https://competition-policy.ec.europa.eu/state-aid/ipcei/approved-ipceis/microelectronics-value-chain\\_en](https://competition-policy.ec.europa.eu/state-aid/ipcei/approved-ipceis/microelectronics-value-chain_en)

<sup>40</sup> [https://competition-policy.ec.europa.eu/state-aid/ipcei/approved-ipceis/batteries-value-chain\\_en](https://competition-policy.ec.europa.eu/state-aid/ipcei/approved-ipceis/batteries-value-chain_en)

<sup>41</sup> [https://competition-policy.ec.europa.eu/state-aid/ipcei/approved-ipceis/hydrogen-value-chain\\_en](https://competition-policy.ec.europa.eu/state-aid/ipcei/approved-ipceis/hydrogen-value-chain_en)

<sup>42</sup> [https://competition-policy.ec.europa.eu/state-aid/ipcei/approved-ipceis/cloud\\_en](https://competition-policy.ec.europa.eu/state-aid/ipcei/approved-ipceis/cloud_en)