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In this edition:

## TARGETED ADJUSTMENTS FOR A FUTURE-READY EU PRODUCT FRAMEWORK



# Table of Contents

<b>EXECUTIVE SUMMARY</b>	<b>03</b>
<b>COMMON DEFINITIONS FOR NEW ECONOMIC ROLES AND PRODUCT LIFECYCLE CONCEPTS</b>	<b>04</b>
<b>TRANSITION TO DIGITAL COMPLIANCE</b>	<b>06</b>



## Executive summary

The new legislative framework (NLF) has been a cornerstone of EU product legislation since its inception in 2008, exemplifying the EU's prowess as a global regulatory leader. Built on principles of presumption of conformity, harmonised standards, technology neutrality and a uniform accreditation system across the EU, the NLF facilitates the seamless movement of goods within the single market. Its most recognisable feature, the CE marking, is a globally trusted symbol of product compliance and safety.

However, recent sectoral legislation – driven by digitalisation and sustainability goals – has expanded the NLF's scope in a fragmented manner. This has introduced legal uncertainty, jeopardising timely product launches and risking delays and costs that Europe cannot afford. Swift deployment of innovative products is vital for restoring EU competitiveness and safeguarding critical infrastructure amidst increasing security challenges.

Whilst a full overhaul of the NLF would create unnecessary instability, we suggest two targeted updates to the Blue Guide and EU harmonisation legislation to address emerging regulatory challenges without disrupting the existing framework.<sup>1</sup> These adjustments will ensure the NLF remains robust, relevant and aligned with evolving technological and environmental priorities:



**Targeted adjustment #1 – Clarify definitions for new economic roles and product lifecycle concepts:** Recent legislation has introduced new roles (e.g. deployer, independent operator, open-source steward) and lifecycle concepts (e.g. substantial modification, refurbishment) without consistent definitions. Establishing clear, universal definitions will enhance legal certainty and support compliance across the EU.



**Targeted adjustment #2 – Enabling digital compliance:** Allowing electronic formats for safety-related product documentation, such as instructions and declarations of conformity, will align with the EU's green goals, reduce administrative burden and facilitate the adoption of digital product passports (DPPs), a centralised tool for compliance data.

These targeted updates will modernise the NLF, fostering innovation, competitiveness and sustainability whilst maintaining the framework's foundational stability.

<sup>1</sup>This paper expands on our broader recommendations on streamlining regulatory requirements across EU legislation contained in our report *Winning the tech race. Cut-simplify-incentivise: Our three-step gameplan*, available at <https://cdn.digitaleurope.org/uploads/2024/11/DIGITALEUROPE-TECH-RACE-REPORT-FINAL-WEB-1.pdf>.





## Common definitions for new economic roles and product lifecycle concepts

The NLF's historical clarity in assigning responsibilities amongst economic operators – such as manufacturers, importers, distributors and conformity assessment bodies – has been key to its success. However, new sectoral laws have introduced roles that lack universal definitions, complicating compliance and enforcement.

Recent sectoral legislation has also introduced new product lifecycle concepts, reflecting trends in digitalisation and circular economy. Inconsistent definitions across laws undermine the NLF's harmonisation objectives.

Clarifying these terms will streamline compliance and support Europe's transition to a circular economy.

### Targeted adjustment #1:

Revise the Blue Guide or amend harmonisation legislation to establish standard definitions for these new roles and lifecycle concepts, ensuring consistent application across the EU.





Examples of **new roles** include:

- ▶ **Deployer** in the AI Act:<sup>2</sup> An entity using an AI system under its control for professional purposes.
- ▶ **Independent operator** in the Ecodesign for Sustainable Products Regulation (ESPR) and Batteries Regulation:<sup>3</sup> An entity involved in supply chain activities like repair, maintenance and repurposing, independent of manufacturers.
- ▶ **Professional repairer** in the ESPR:<sup>4</sup> A service provider for repair or maintenance, whether affiliated or independent.
- ▶ **Open-source software steward** in the Cyber Resilience Act (CRA):<sup>5</sup> A facilitator of open-source digital product development for commercial use.<sup>6</sup>

Key **product lifecycle concepts** requiring harmonisation include:

- ▶ **“Commercial activity” in the context of free and open-source software (FOSS):** Present in the CRA as part of the definition of “making available on the market”,<sup>7</sup> it is meant to characterise FOSS monetisation but fails to fully capture the diverse and evolving business models within the open innovation ecosystem.<sup>8</sup>
- ▶ **Refurbishment:** Focused on restoring performance, as outlined in the ESPR and Batteries Regulation.<sup>9</sup>
- ▶ **Remanufacturing:** Defined in the ESPR and Batteries Regulation, involving significant changes to safety, performance or purpose.<sup>10</sup>
- ▶ **Substantial modification:** Present in the AI Act, Machinery Regulation, General Product Safety Regulation (GSPR) and CRA, yet inconsistently defined.<sup>11</sup>
- ▶ **Spare parts handling:** Mentioned in the ESPR and Batteries Regulation but ambiguously scoped regarding non-safety-critical parts.<sup>12</sup>

<sup>2</sup> Art. 3(4) Regulation (EU) 2024/1689.

<sup>3</sup> Arts 2(47) Regulation (EU) 2024/1781 and 2(3) Regulation (EU) 2023/1542.

<sup>4</sup> Art. 2(48) Regulation (EU) 2024/1781.

<sup>5</sup> Art. 3(14) Regulation (EU) 2024/2847.

<sup>6</sup> Guidance in the CRA, including examples and case studies, must offer legal clarity to open-source organisations that may simultaneously act as manufacturers and open-source stewards. We suggest the guidelines clearly specify that upstream FOSS organisations can, in some cases, also be considered manufacturers, regardless of their legal form or structure.

<sup>7</sup> Art. 3 (21) (22) Regulation (EU) 2024/2847

<sup>8</sup> More information on this in DIGITALEUROPE, Developing guidelines for the CyberResilience Act (7-9), available at [https://cdn.digitaleurope.org/uploads/2024/09/Developing-guidelines-for-the-Cyber-Resilience-Act\\_DE.pdf](https://cdn.digitaleurope.org/uploads/2024/09/Developing-guidelines-for-the-Cyber-Resilience-Act_DE.pdf)

<sup>9</sup> Art. 2(18) Regulation (EU) 2024/1781 and Annex XIV(2)(b) Regulation (EU) 2023/1542.

<sup>10</sup> Arts 2(16) Regulation (EU) 2024/1781 and 2(16) Regulation (EU) 2024/1781.

<sup>11</sup> Art. 3(23) Regulation (EU) 2024/1689, Art. 3(16) Regulation (EU) 2023/1230, Recital 35 Regulation (EU) 2023/988 and Art. 3(30) Regulation (EU) 2024/2847.

<sup>12</sup> Arts 5(2) Regulation (EU) 2024/1781 and 11(7) Regulation (EU) 2023/1542.



## Transition to digital compliance

Despite 91 per cent of the EU population having internet access,<sup>13</sup> the NLF still mandates paper-based product documentation, such as instructions and safety information. This approach contradicts the EU's green goals and objective to reduce administrative burden by 25 per cent.

### Targeted adjustment #2:

**Permit electronic formats for safety-related product documentation as an alternative to paper, aligning with the role of DPPs.**

#### Rationale:

- ▶ DPPs, now mandatory under the ESPR, serve as central repositories for product information, accessible via QR codes, RFID tags or similar data carriers.
- ▶ Allowing compliance data – such as the CE marking and declaration of conformity – to be integrated into DPPs will reduce paper usage and facilitate streamlined regulatory processes.
- ▶ Draft regulations for toy safety and construction products already support digital compliance, setting a precedent for broader adoption.<sup>14</sup>

This adjustment will simultaneously advance sustainability goals, enhance regulatory efficiency and reduce costs for businesses.

<sup>13</sup> Eurostat, Digital economy and society statistics – households and individuals, available at [https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Digital\\_economy\\_and\\_society\\_statistics\\_-\\_households\\_and\\_individuals&olid=636336](https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Digital_economy_and_society_statistics_-_households_and_individuals&olid=636336)

<sup>14</sup> COM(2023) 462 final and COM(2022) 144 final, respectively.







# DIGITALEUROPE

DIGITALEUROPE is the leading trade association representing digitally transforming industries in Europe. We stand for a regulatory environment that enables European businesses and citizens to prosper from digital technologies.

We wish Europe to grow, attract and sustain the world's best digital talents and technology companies. Together with our members, we shape the industry policy positions on all relevant legislative matters and contribute to the development and implementation of relevant EU policies.

Our membership represents over 45,000 businesses that operate and invest in Europe. It includes 108 corporations that are global leaders in their field of activity, as well as 41 national trade associations from across Europe.

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