A New Legislative Framework for the Next Decade

Answer to the Commission's Call for Evidence «Product legislation – ensuring futureproof rules (revision of the New Legislative Framework - NLF)»

bitkom

At a glance

Revision of the New Legislative Framework

Initial position

Since its introduction, the New Legislative Framework (NLF) has been instrumental in facilitating efficient and fair market access within the EU, laying a strong foundation for regulatory coherence and consumer protection. The evolving product landscape, highlighted by the rapid growth of digital products and increased life-cycle demands, offers a great chance to update and improve the framework for future success.

Bitkom rating

Bitkom calls for **targeted legislative updates** to adapt the NLF to new challenges while **preserving its two core principles**: i) Setting essential requirements in legislation and providing the primary technical means of meeting those requirements with harmonised standards and (ii) a risk-based modular conformity assessment system—especially Module A, which enables low-burden in-house compliance.

The most important takeaway

We believe the following actions will bring the NLF up to date, while providing simplification and reducing unnecessary compliance burdens:

- **Aligning NLF requirements across NLF acts**

  Address the growing complexity and uncertainty caused by fragmented and sometimes contradictory requirements in different NLF legislations by setting common requirements for products under the NLF.

- **Updating the applicability of the NLF to non-tangible software products**

  Re-assess definitions and processes under the NLF to adequately include the specific characteristics of software (e.g., dependence on execution environments), its development (e.g. up to daily new product versions) and its distribution (e.g. download links, app stores).

- **Clarifying the responsibilities of economic operators over the product lifecycle**

  Introduce clear and coherent responsibilities for economic operators with a focus on feasibility, especially in the context of software updates and replacement parts.

- **Ensure the legally compliant supply of spare parts**

  Adapt requirements such that components intended as spare parts should only be required to comply with the NLF legislation that was applicable at the time the (original) product to be repaired was placed on the market.

1 The NLF as an essential tool for the European market

Since its introduction, the New Legislative Framework (NLF) has proven to be a vital instrument for ensuring efficient and fair market access in the EU. Bitkom believes that two core principles have contributed to its success:

- Setting essential requirements in legislation and providing the primary technical means of meeting those requirements with harmonised standards
- The risk-based modular system for conformity assessment, especially Module A, which allows an assessment in-house, enabling low-burden compliance

However, these principles and the effectiveness of the NLF have come under increasing pressure. We believe four areas should be addressed by the revision:

1. The product and regulatory landscape has changed to include digital technologies such as AI and cybersecurity, as well as a growing focus on circular economy and requirements on products over their lifecycle. Software products fall under the existing NLF definitions and processes, which were largely developed for tangible goods. The **NLF needs to be updated to accommodate this changing landscape**.
2. New NLF-based legislations have introduced an **increasing number of exceptions and specificities**, such as including provision for spare parts under the CRA only, resulting in a fragmented landscape of requirements even for single products—and placing an ever-growing burden on manufacturers.
3. The **slow listing of harmonised European standards in the Official Journal of the EU**, as well as the blocking of citation of international standards, leads to legal uncertainty for manufacturers and builds barriers for international trade.
4. The broad **introduction of common specifications** through the Omnibus IV as an alternative to harmonised standards risks sidelining stakeholder participation in the development of the technical implementation of regulatory requirements.

We therefore advocate for **targeted legislative changes that reinforce and restore the NLF's strength while retaining the two core principles** – separation of essential requirements from technical specification, and modular conformity assessment – with a strong focus on simplification and reducing unnecessary burdens. **Especially the Commission's «Proposal 3: Align the NLF" serves this goal, and we provide essential suggestions what the alignment should include**. We believe the NLF revision should lead to a reduction in bureaucratic effort, increase efficiency and competitiveness of European industry and make the NLF an effective tool for the upcoming years.

2 Keep or Toss?

Response to the Commission's Proposals for Improving the NLF

The Commission proposes five legislative options in the call for evidence. We address each.

Proposal 1: Increasing Digital Integration

Bitkom supports end-to-end digitalisation of the compliance process but stresses that digitalisation needs to occur effectively. We argue:

1. The Digital Product Passport is not a silver bullet – pursue broader digitalisation

While the Digital Product Passport (DPP) is an important tool, it is not the only and not an isolated path to digitalisation. Bitkom encourages the Commission to continue exploring and aligning other digitalisation opportunities, particularly those missed in the Omnibus IV proposal. These include:

- Voluntary full digitalisation of safety instructions
- E-labelling for applicable product classes
- Elimination of mandatory postal address requirements where digital contact options suffice.

These measures would reduce costs, lower administrative burdens, and improve flexibility for manufacturers without compromising safety or consumer protection.

2. Not on its own – Align and integrate the DPP with other projects

An alignment of the DPP with several digital initiatives within the EU is vital to exploit its full potential, and to boost digitization in Europe's quality infrastructure (standardization, conformity assessment, accreditation, metrology, and market surveillance). One critical aspect is the integration of the DPP with the EU Business Wallet. It is also crucial to consider the various digitization efforts of the member states, e.g., respective market surveillance.

The European DPP should have global impact and serve as role model for international DPP standardization. This will be beneficial for European competitiveness and significantly reduce bureaucracy and implementation costs for all stakeholders.

3. Digital ≠ cheap – systematically assess the DPP's effectiveness

Bitkom supports the introduction of a DPP as a horizontal tool to improve transparency, traceability, and sustainability across value chains. However, the current design risks turning the DPP into an additional cost burden for manufacturers rather than a useful instrument. In particular, its reliance on third-party service providers and mandatory third-party backups will drive up costs for SMEs, who stand to benefit the least. We therefore urge the Commission to perform a targeted impact assessment to

ensure the DPP is designed as an efficient, value-adding tool before rolling it out on a broad scale.

4. Who sees what? – Clarify access and intentions

The DPP is not yet a mature or tested instrument. A key unresolved issue remains a strong and secure concept for «need-to-know» data access, guaranteeing at once the benefits for market surveillance and protecting sensitive proprietary and commercially sensitive data. Broad data access, as suggested in the recent IMCO report[1], would risk violating trade secrets and IP rights. We ask the Commission to clarify its intentions by specifying what documentation should foreseeably be included.

5. Keep design technology neutral

EU lawmakers should not limit the technology of accessing a DPP to just QR codes and instead allow selecting alternative solutions. Examples include products where a line of sight for scanning is hard to achieve and Near Field Communication (NFC), Radio Frequency Identification (RFID), or Bluetooth would provide more appropriate solutions.

Proposal 2: Strong conformity assessment processes

The modular system of conformity assessment allows a product-targeted conformity assessment and has proven robust and functional. Module A, which allows an assessment in-house, is particularly effective in enabling low-burden compliance and has become an invaluable tool for manufacturers.

However, we acknowledge that number of modules and variations, combined with the simultaneous application of multiple NLF regulations to a single product, creates significant complexity during assessment. We therefore encourage the Commission to **evaluate which modules in Annex II of Decision 768/2008/EC are used in practice by industry** and assess whether certain modules can be consolidated without compromising the system's flexibility.

Harmonised European standards should remain the preferred solution for the technical concretization of legal requirements and gaining presumption of conformity. The Commission's recent Omnibus IV proposal[2] introduces common specifications across the NLF. Bitkom strongly recommends the following:

- Under the NLF, common specifications should be clearly limited as a fallback option.
- **Legislation on common specifications should be aligned with Article 20 of the Machinery Regulation**, which sets clear conditions and procedures for the adoption of common specifications.
- Common specifications must be developed with affected stakeholders involved.

[1] Procedure File: 2024/2119(INI) | Legislative Observatory | European Parliament
[2] Digitalisation and alignment of common specifications - European Commission

Proposal 3: Align the NLF

Bitkom strongly supports aligning definitions across the NLF in accordance with Regulation (EU) 2019/1020 on market surveillance—particularly key terms such as «placing on the market" and economic operators, including «fulfilment service provider". However, aligning the NLF with current market needs goes beyond that. We identified four key actions essential in aligning the NLF into a coherent framework.

1. Align requirements across acts to reduce complexity

Products are often subject to multiple NLF regulations and must comply with non-harmonised or even contradictory requirements across different legal acts. This regulatory fragmentation signifies immense complexity, has led to growing uncertainty for manufacturers, and significantly increased their compliance burden.

We therefore urge the Commission to pursue a comprehensive harmonisation of requirements that apply horizontally to all products. Derogations or sector-specific requirements in individual legislative acts should be permitted only where technically justified by the nature of the product or sector.

> *Example*: Only the Cyber Resilience Act (CRA) and some implementing acts under the ESPR act currently includes clear provisions on spare parts, leaving a legislative gap and uncertainty in other sectors.
>
> *Example*: Several acts under the NLF require the identifier of the notified body that assisted in the conformity assessment to follow the CE mark. It is unclear, which of the identifiers should come first.

Additionally, referencing other NLF acts in a legislation creates complex cross connections and interactions, which are potentially even contradictory. We recommend reducing cross complexity.

> *Example*: Under the AI Act, every AI system that is a product or safety-component of a product that falls under an external certification obligation under the Medical Device Regulation is automatically high-risk under the AI Act, even if harmless.

2. Update the applicability of the NLF for software products and hardware components

With the introduction of the Cyber Resilience Act (CRA), pure software products and hardware components will also be subject to product regulation by the NLF. However, with the integration of immaterial software products and hardware components, many definitions, and procedures of the NLF designed for physical end products are no longer clearly applicable.

We recommend evaluating established NLF terms on their applicability to software products and hardware components. We exemplify how certain terms, among others, remain unclear:

Placing on the market: When is a software product considered to be «*placed on the EU market*"?

- When it is published on the Internet via a download link?
- When it is downloaded?
- When the software licence is activated?
- When it is provided to the consumer as a Software as a Service?

How can the concept of placing on the market account for the specific role of hardware components as well as specific challenges related to their design, development, manufacturing, and sector? A practical definition is crucial to avoid supply chain disruptions and disproportionate compliance burdens, especially for critical components, such as semiconductors.

Making available on the market: Does an intangible copy of a software product represent the same product, and is therefore «*made available*" on the market?

Recall: Does recalling include deactivating a user's licence, or asking users to delete the software?

Affixing the CE mark: How does one affix the CE mark on a software product that is made available over third parties, for example within an app store or software repository?

Substantial modification: How can one practically determine if an update constitutes a substantial modification and provide a conformity assessment in the context of fast-moving software products, e.g., agile software development with up to daily new product versions?
How does the concept of substantial modification apply to embedded systems?

Consider dependency on non-EU products
We would also like to point out possible dependencies on non-EU software products that remain essential for many EU software products but do not comply with the NLF, especially during a critical transition period after regulations become active. Examples are cloud environments, operating systems, and software libraries.

Consider context dependency
Many components and software products cannot be assessed in isolation, as their compliance depends heavily on their operating environment. For components such as semiconductors, compliance depends on integration into the final product, often unknown to the manufacturer. For software, behaviour and compliance can change with its execution environment (e.g. operating system updates, security patches, or bug fixes). We therefore encourage clarification of the extent of a manufacturer's responsibility for such components or software.

3. Ensure the legally compliant supply of spare parts:

Spare parts that fall within the scope of a CE regulation must currently meet the same state-of-the-art conformity as new products when supplied as such. This creates challenges because spare parts are often intended for products that comply with an older state of the art and legislation (which was applicable at the point in time when the product has been placed on the market) than the currently applicable state of the art. These spare parts often cannot be adapted to the latest requirements. Such spare

parts, which are used exclusively for repair and not intended for use in newly manufactured products, can often no longer be adapted to the current state of the art, or adaptation would render them unsuitable as spare parts. This impedes that such parts are supplied and prevents or complicates the repair of defective products or systems. Sustainability goals and the economic interests of operators or users of products are undermined. Furthermore, operators/users are «penalized» because their product has a defect.

We therefore recommend the following principle: **Components intended as spare parts should only be required to comply with the NLF legislation that was applicable at the time the (original) product to be repaired was placed on the market.** This ensures that the current state of technology for the product to be repaired is maintained, and no disadvantages are created with regard to legal protection targets.

Possible legal text:

«This [Legal act] does not apply to products that are exclusively made available on the market as spare parts to replace identical components in products to be repaired and that are manufactured according to the same specifications as the components that they are intended to replace.»

4. Clarify and evaluate responsibilities of economic operators

The NLF should establish clear and proportionate rules on the responsibilities of economic operators, taking into account evolving roles, technologies, and lifecycle considerations. In particular:

Evaluate, for each economic operator under the NLF, if the currently assigned total responsibility is still feasible.
Example: For a distributor operating a large warehouse, is it feasible to require full compliance with Article R5(2) of Decision 768/2008/EC by opening every package to check conformity markings?

Clarify responsibilities with regard to new roles and requirements on lifecycle
Clear guidance is needed on how responsibilities are shared when products are refurbished, repaired, or upgraded, and how these apply to new product categories introduced under the NLF, such as software.

Proposal 4: Reliable Notified Bodies

We are increasingly concerned that there will be too few notified bodies once new legislation, such as the CRA, takes effect. This issue cannot be solved through stricter oversight alone; its root cause lies in the growing volume of regulations and delays in citing harmonised standards, which together strain the conformity assessment system. However, where notified bodies are lacking in number or capacity, manufacturers must not face market access delays. Bitkom therefore calls for clearer obligations for notified bodies, particularly where their involvement is mandatory:

- The NLF should establish binding timelines or deadlines for notified bodies to complete conformity assessments to protect especially SMEs with less bargaining power from delays in assessment.

- Where such deadlines are not met, the affected product should benefit from a presumption of conformity with the relevant harmonisation legislation, ensuring that delays on the part of notified bodies do not unjustly hinder market access.

These improvements would protect innovation timelines and ensure that bottlenecks in conformity assessment do not become a barrier to European competitiveness.

Proposal 5: Consistent Responses to Non-Compliance

Bitkom identifies four key problems in the current enforcement of compliance by market surveillance authorities:

1. inability to keep pace with the growing volume of regulations and new digital-sector requirements;
2. in Germany, extreme fragmentation of responsibilities, with multiple points of contact for different regulations within the same sector and across regional and national levels;
3. difficulty in testing certain specialised or rare products, which often require costly tools that authorities lack;
4. lack of tools to enforce conformity in online sale, as the legislation defines no importer or authorized representative within the EU against whom recourse could be taken.

Bitkom therefore strongly supports strengthening market surveillance to ensure consistent enforcement and a level playing field across the Single Market. To achieve this, we recommend:

- **increasing financial and human resources** for market surveillance authorities, along with **stronger incentives and obligations** for Member States to guarantee effective enforcement;
- **establishing an EU-level coordination body** (e.g. a central agency) to handle rare test cases, pool expertise, and share specialised testing equipment for greater efficiency;
- **revising roles and responsibilities in the context of online sale** to allow for recourse by market surveillance authorities.

Bitkom represents more than 2,200 companies from the digital economy. They generate an annual turnover of 200 billion euros in Germany and employ more than 2 million people. Among the members are 1,000 small and medium-sized businesses, over 500 start-ups and almost all global players. These companies provide services in software, IT, telecommunications or the internet, produce hardware and consumer electronics, work in digital media, create content, operate platforms or are in other ways affiliated with the digital economy. 82 percent of the members' headquarters are in Germany, 8 percent in the rest of the EU and 7 percent in the US. 3 percent are from other regions of the world. Bitkom promotes and drives the digital transformation of the German economy and advocates for citizens to participate in and benefit from digitalisation. At the heart of Bitkom's concerns are ensuring a strong European digital policy and a fully integrated digital single market, as well as making Germany a key driver of digital change in Europe and the world.

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