VDMA

TECHNICAL AFFAIRS AND STANDARDISATION

POSITION PAPER

A Trusted System, Finely Tuned: Enhancing the **New Legislative Framework** for Simplicity and Coherence

Registration number in the register of EU-Transparenzregister ID: 9765362691-45

August 2025

VDMA is Europe's largest business association advancing Europe's machinery industry. We primarily represent small and medium sized enterprises (SME's - over 80% of the membership) in Austria, the Benelux states, Italy, Poland and Germany.

Past, Present and Future of Trade in Europe

The New Legislative Framework (NLF) and before it, the New Approach, are among the most successful, innovative and influential legislations of the EU. They helped tie a diverse market together, to form the common European market, where goods can flow across state borders. In the spirit of simplification and coherence we endorse a light touch legislative policy option of the commission to improve on the current NLF in certain areas, while maintaining its core principles.

Overview of the Needs of the European Manufacturing Industry to Future-Proof the NLF

1. **Issues and Challenges with Harmonised Standards and Its Threat to the NLF** (Chapter 1)
    a. The process to obtain harmonised standards from the standardisation request to the listing in the OJEU should be accelerated and simplified.
    b. Harmonised standards should be able to be based on international standards from ISO and IEC.
2. **Digital Integration of the Internal Market and the Proportional Introduction of the Digital Product Passport (DPP)** (Chapter 2)
    a. The digitisation of documentation is a pragmatic first step. It is important that any system put in place remains interoperable with the DPP under the Ecodesign for Sustainable Products Regulation (ESPR), without duplicating efforts or creating new burdens for businesses. The DPP should act solely as a digital container for existing documentation — such as the EU Declaration of Conformity and user instructions — enabling competent authorities to perform more effective market surveillance.
3. **Revision of Conformity Assessment by Strengthening Module A** (Chapter 3)
    a. The Commission should strengthen the application of Article 4(1d) of Decision 768/2008/EC and prioritize the possibility to use Module A wherever the product risk allows, ensuring proportionality and preserving innovation capacity in European industry.
    b. The trend towards increased mandatory third-party certification should be critically reassessed, as it risks diverting scarce STEM[1] resources from

[1] (**STEM**) Scientific, technology, engineering and mathematics

innovation and weakening market surveillance. To amend past regulation, a "conformity assessment simplification" omnibus should be introduced.

4. **Alignment of Definitions and Provisions Across Legislative Acts** (Chapter 4)
    a. Definitions and Provisions should be harmonised and simplified across legislative acts. Furthermore, any deviation to the letter from previously established definitions and provisions should be explained in recitals.
5. **Beyond Alignment: Reduction of Administrative Burdens in Product Regulation** (Chapter 5)
    a. Achieving the Commission's ambitious goal of reducing administrative burdens by 25% (35% for SMEs) requires building the capacity and competence to systematically screen existing product legislation and eliminate disproportionate requirements, as alignment with NLF provisions alone will not suffice.
6. **Clarifying the Regulatory Framework for Remanufacturing and Refurbishment** (Chapter 6)
    a. Future Delegated Acts under the ESPR should avoid narrowly defining "substantial modification" and instead provide clear guidance and exemptions to manage overlaps between regulatory frameworks. Only the legal acts actually triggered by a modification should require a new declaration of conformity, while partial remanufacturing or component upgrades should not automatically demand a full CE reassessment.
    b. Remanufacturers should fully assume manufacturer responsibility, including marking obligations, without requiring original manufacturers to disclose technical documentation, thereby safeguarding intellectual property while ensuring consumer safety.
7. **Functioning, Localisation and Oversight of Notified Bodies** (Chapter 7)
    We fully support the Commission's intention to significantly reinforce the oversight of notified bodies, with particular emphasis on outsourcing to third countries, requiring prior disclosure to manufacturers, and ensuring transparency through reporting of subcontracting arrangements in the NANDO database.
8. **Timely and Consistent Response to Non-Compliant and Dangerous Products** (Chapter 8)
    a. The Commission should establish a centralized EU market surveillance authority to improve coordination between national and customs authorities.
    b. Companies with repeated safety violations should be excluded from using Module A and required to undergo third-party conformity assessments by notified bodies.

1 Preserving the Success of the NLF: A Careful Approach to Legislative Optimisation

For VDMA companies the New Approach, followed by the New Legislative Framework (NLF) has been the original simplification of product regulation. Therefore, we hope the commission, which has proclaimed "*simplification the most salient objective of this revision*", will keep in mind the following three aspect, on which the success of the NLF was built on:

1. harmonising product regulation across Europe
2. separating safety provisions in the law from their technical specifications in harmonised standards
3. enabling conformity assessment by the manufacturer – often referred to as Module A –

We believe that recent NLF regulations have strayed especially from the last two core pillars. Therefore, **we encourage the commission to opt for a careful legislative optimisation of the NLF,** with the aim of strengthening this fundamental European legislation.

In the following we will comment on the legislative options suggested by the commission and outline our view on certain matters in addition to the suggestions by the commission.

Beyond the scope of this call for evidence lies a cornerstone institution of the NLF: standardisation. Yet this crucial tool is currently stalling:

- The process from creating a standardisation request to listing harmonised standards is currently too time-intensive[2] and cumbersome. At the same time, any acceleration of the process should ensure that technical experts retain sufficient time to carry out the core standardisation work thoroughly.
- Furthermore, developing harmonised standards as ISO/IEC standards under the Vienna/Frankfurt-agreement has greatly facilitated trade beyond the borders of the European common market thus far. However, this productive practice has currently stopped. **If this challenge continues, the damage to our industry will outweigh any possible improvements that could be yielded by reworking the NLF, as the machinery industry exports roughly 80% of its products beyond Europe's borders. The international compatibility of harmonised standards must therefore be**

[2] As per Table 4 (S. 28) of the evaluation of regulation 1025/2012 the average durations in 2024 of the phases to obtain harmonised standards are: Phase A: adoption & notification of standardisation request (**1.7 years**), Phase B: Delivery of the standard (**3.2 years**) and Phase C: Submission and publication (**1.2 years**)

restored. Joint ISO/IEC - CEN/CENELC standardization can get disturbed due to the unpredictability of the harmonization process.

2 Digital Integration of the Internal Market and the Proportional Introduction of the Digital Product Passport (DPP)

We support the digital sharing of certain documentation – EU declaration of Conformity and instructions - as a key measure to enhance digital integration within the European internal market. This approach facilitates streamlined compliance and data access, reducing fragmentation across Member States. However, we do not consider the implementation of a full Digital Product Passport (DPP) system necessary for this purpose. We believe that the DPP should only be mandatory for products regulated under ESPR delegated acts and, in that context, be linked to and include the relevant technical documentation. The principles on the digitisation of documents proposed by the Omnibus IV regulation, represent a potential path forward under the condition that the mandatory content is limited to the necessary minimum. These principles enable the digitisation of documentation without overburdening the companies by having to introduce a complex DPP immediately. Furthermore, it contains provisions on unifying access to digital documentation, by making the DPP the one-stop-shop once an ESPR delegated act makes it obligatory (e.g. COM(2025)504 Art.5 (9)).

The digitisation of documentation is a pragmatic first step. It is important that any system put in place remains interoperable with the DPP under the Ecodesign for Sustainable Products Regulation (ESPR), without duplicating efforts or creating new burdens for businesses. The DPP should act solely as a digital container for existing documentation — such as the EU Declaration of Conformity and user instructions — enabling competent authorities to perform more effective market surveillance by quickly identifying cases of obvious non-compliance. These authorities should continue to be able to request the underlying conformity assessment documentation directly from the manufacturer when needed.

To ensure that these provisions have a positive effect on the ease of enforcement of the common market rules by market surveillance, it is vital that the economic operators listed in Article 4 of the Market Surveillance Regulation (EU) 2019/1020 — meaning manufacturers, importers, authorised representatives, and fulfilment service providers — have to ensure the information required is stored within the DPP, including details on the mandate and validity of the EU representative.

Furthermore, we believe that the deliberate misrepresentation of non-existent EU representatives or data garbage instead of DPP relevant documentation should result in exclusion from the EU market or the imposition of mandatory third-party certifications (as described in chapter 8) (and/or fines).

3 Revision of Conformity Assessment by Strengthening Module A

Chief among our needs is a shift of the NLF as described in

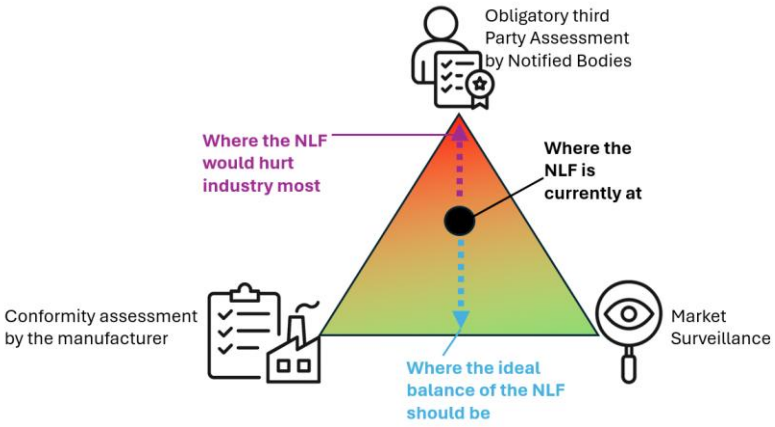

Figure *1*. To cut regulatory burden, industry needs the comprehensive possibility to choose Module A as described in Annex II of the regulation 768/2008/EC, also known as “conformity assessment by the manufacturer”. It has enabled companies to bring products safely and speedily to the European market. The use of Module A in conformity assessment allows new technical solutions and technologies to be brought to market quickly, while also ensuring the timely delivery of customized solutions. This should be coupled with a strengthening of market surveillance authorities.

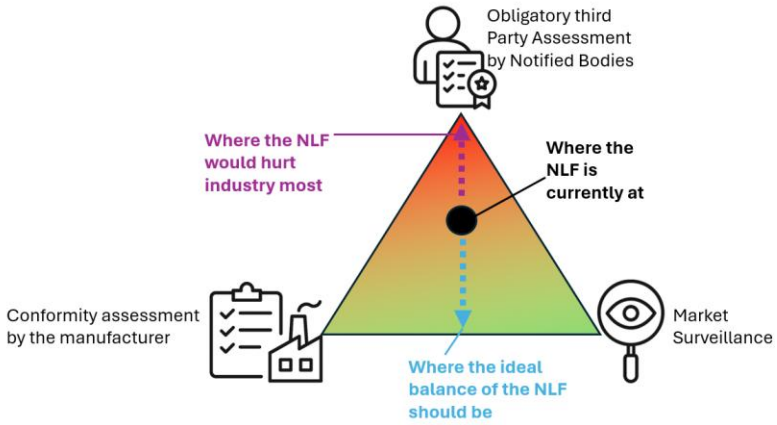

Figure 1 – Triangle depicting the balance between conformity assessment by the manufacturer, market surveillance and obligatory third-party assessment by notified bodies.

The European mechanical engineering industry has a unique selling point in these areas, which must be maintained in the face of tough international competition. Due to the facilitation in market access regulation that was introduced with the Module A, the already high safety level of technology in Europe has consistently improved. **Technology engineered in Europe, starting from a high level, is consistently becoming safer. Nevertheless, recent legislation has been pushing for more third-party certification.** Considering the provision under Art. 4 (1d) of Decision 768/2008/EC that the legislator should

"*avoid imposing modules which would be too burdensome in relation to the risks covered by the legislation concerned*"
a proportionate recalibration is necessary, by aligning the selection of conformity assessment modules with the actual risk presented by products. The growing trend towards mandatory third-party certification should be critically examined—particularly considering the continuous development of the state of the art, the demographic change and a shortage of engineers across Europe.[3] Expanding mandatory third-party assessments could reduce productivity by diverting scarce engineering resources from companies' innovation departments to third party assessment bodies. In addition, this technical expertise would then also be lacking in market surveillance authorities, weakening this core government function. Regardless of the modules required in the NLF regulations, industry and market surveillance will always have to adapt the size of their workforces to ensure compliance with product regulation. In contrast, the size of the third-party conformity assessment workforce is something that lawmakers can directly influence by enabling or disabling the use of Module A (Figure 2). This problem is especially prominent in

[3] In Germany alone the current STEM labour market gap is more than 150 000. Note, that only just in January of 2023 had the gap grown to nearly 350 000 (for details see Link – page 4). The labour market gap is calculated by subtracting the number of people searching STEM for jobs from the number of STEM job openings.

new technology fields, such as cybersecurity and artificial intelligence, where there are limited resources, knowledge, a limited number of notified bodies and the lack of supporting standards generating risks for significant divergence between assessments.

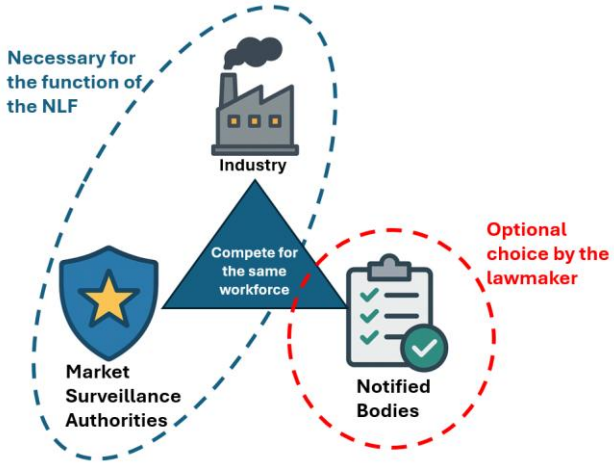

Figure 2 – Distinct areas in which STEM employees are needed to ensure the functioning of the NLF.

In the spirit of simplification, enforceability of regulation and the reduction of regulatory burden, we urge the commission to apply Art. 4 (1d) of Decision 768/2008/EC targeting competitiveness and to make greater use of conformity assessment by the manufacturer than has been the case to date. **To amend past regulation, a "conformity assessment simplification" omnibus should be introduced.**

4 Alignment of Definitions and Provisions Across Legislative Acts

We welcome the effort to harmonize definitions used across different legislative instruments—particularly between the NLF and Regulation (EU) 2019/1020 on market surveillance. Clear and consistent terminology significantly improves legal certainty. Wherever possible, definitions should be used consistently to avoid unnecessary gaps in interpretation and inconsistent application.

This alignment should go beyond definitions. The template for how to legislate product regulation, found in Decision 768/2008/EC has successfully harmonised key parts of currently 30 regulations under the NLF. The practice of regulatory alignment through consistent application of the model provisions and definitions of Decision 768/2008/EC without amendments should be continued. This principle should be extended to legislative tools originally introduced in one harmonised act, which are then extended to acts adopted after it.

Current example of where this did not work: The Omnibus IV [COM(2025)503/4] is an example of incoherence in the legislation. Articles on how to introduce “Common specifications” (CS) were already present in other NLF regulations, such as the Machinery Regulation (2023/1230, Art. 20), the Cyber Resilience Act (2024/2847, Art. 27) and others. Nonetheless, Omnibus IV suggests introducing CS in several NLF regulations (and beyond) based on new criteria and a different comitology approach, from what had been used before. Such misalignment should not happen.

Suggestion on how to remedy this in the future NLF (Article 2 of Decision 768/2008/EC should be expanded as follows): “*If Union legislation departs from the general principles and provisions of Annexes I, II and III, or from other previously established legal principles, a recital shall be necessary to justify and explain the departure. The law makers, especially the Commission as the guardian of the treaties, shall be responsible for ensuring that only necessary departures are made and no departure from the letter of the template shall be left unexplained in a recital. “*

We believe that the process of making laws would be made significantly more efficient in producing good regulations, if it consistently had to explain, why a deviation from a template was introduced.

5 Beyond Alignment: Reduction of Administrative Burdens in Product Regulation

Aligning future legislation with the NLF model provisions alone will not eliminate existing disproportionate or unnecessary requirements. To achieve meaningful simplification, a systematic screening of existing Union product legislation is required, with the objective of removing or reducing such requirements. At present, however, the Commission lacks the structure, competence and capacity to carry out this task, and we therefore encourage it to strengthen both.

A powerful lever: The European Commission has committed to reducing administrative burdens in the EU by at least 25%, and by at least 35% for SMEs, as stated in its work programme. **We fully support this Commission goal!** This reduction target could be operationalised as a mandate to Commission services, including desk officers and Standing Committees, to identify and remove redundant or disproportionate provisions in current product legislation. Without a significant contribution from product regulation, the Commission will probably not reach its own ambitious goal.

6 Clarifying the Regulatory Framework for Remanufacturing and Refurbishment

The need for consistency and legal clarity is also critical when it comes to remanufacturing and refurbishment: both essential for advancing the circular economy in mechanical engineering. These practices are only viable if they are supported by coherent regulatory frameworks.

We welcome that the Ecodesign for Sustainable Products Regulation (ESPR) for the first time defines and differentiates between the two concepts. Remanufacturing refers to an industrial process that creates a new product consisting of old and new parts and components, requiring full compliance with current product legislation, including CE marking. Refurbishment, on the other hand, restores a used product to a functional state, without necessarily meeting all original specifications. Clear labelling (e.g., “refurbished by”) is essential to prevent confusion about responsibility and liability.

Despite this clarity, the mechanical engineering industry continues to face uncertainty due to overlapping and sometimes contradictory requirements across regulations such as RoHS, REACH, the Cyber Resilience Act and the Machinery Regulation. For example, new substance restrictions introduced after a product’s first market entry may conflict with remanufacturing efforts.

To address these issues, future Delegated Acts under the ESPR should not narrowly define when a modification qualifies as a substantial modification, as this would overly regulate and restrict innovation and the potential for future technological repurposing and remanufacturing processes. Instead, they should focus on providing guidance and clear exemptions to manage overlaps between different regulatory frameworks. For example, if the assessment of a machine retrofit indicates a substantial modification under the Machinery Regulation, it would be disproportionate to require the entire modified machine to fully comply with RoHS, REACH, and CRA according to the latest standards, especially when the original machine was placed on the market before these regulations applied. A more appropriate approach would be to determine, during the modification, which legal acts are triggered by the substantial change and apply only those, with the modifier issuing a declaration of conformity for the applicable acts along with the results of the assessment for the others. In some cases, partial remanufacturing or component upgrades should not require a full CE conformity reassessment.

Additionally, **the original manufacturer should not be obligated to share technical documentation, preserving intellectual property**. Remanufacturers must assume full manufacturer responsibility, including marking obligations. This ensures product safety for consumers, while protecting the investments and reputations of original manufacturers.

7 Functioning, Localisation and Oversight of Notified Bodies

We fully support the Commission's intention to significantly reinforce the oversight of notified bodies. A particular focus must be placed on the growing trend of outsourcing conformity assessment tasks—or related activities to entities based in third countries. When an EU Notified Body offers conformity assessment services that are to be performed outside the EU, this should be clearly disclosed prior to the offer and again at contract agreement—allowing the manufacturer the option to seek another EU-based Notified Body if desired. Furthermore, Notified Bodies should be required to report on subcontracting arrangements involving non-EU entities, with this information published in a consolidated format via the NANDO database.

Further suggestions to improve the oversight of notified bodies:

- In the event that an EU Notified Body is being sold, a right of first purchase should be granted to other EU-based Notified Bodies.
- If an EU Notified Body is acquired by a non-EU entity, all documentation should first be offered to other EU Notified Bodies before the transaction is completed. If no interest is expressed, the documentation could be transferred to a central authority or held in trust by the relevant national accreditation body.

8 Timely and Consistent Response to Non-Compliant and Dangerous Products

The lack of speed and consistency in responding to non-compliant or dangerous products continues to be a critical weakness in the EU's market surveillance framework. We strongly support closer coordination between national authorities and other involved stakeholders like national customs and "health and safety" authorities and advocate for the creation of a centralized **EU-level market surveillance body. However, this must be designed to streamline coordination, oversight, avoid unnecessary bureaucracy, and make full use of existing expertise**—with the goal of building a coherent, EU-wide enforcement mechanism.

We also recommend a stronger link between market surveillance outcomes and conformity assessment rules. **Companies that repeatedly place unsafe products on the market—thereby exposing serious flaws in their compliance systems or production processes should lose the privilege of using Module A (self-declaration)**. Instead, they should be required to undergo mandatory third-party assessments, conducted by notified bodies located

within the EEA. This measure should be fully aligned with enhanced oversight of notified bodies (see Chapter 7).

Importantly, these challenges are not limited to product safety. Market surveillance authorities are already under pressure when it comes to enforcing environmental and sustainability standards. EU data clearly show that gaps exist, e.g. in the case of REACH-related restrictions, market surveillance is largely unable to enforce prohibitions on substances where thresholds are set at trace levels. With the upcoming Ecodesign for Sustainable Products Regulation (ESPR) set to expand the number of regulated products and introduce new, often qualitative criteria like carbon footprint and recycled content, businesses are concerned that enforcement will fall even further behind.

Given the increasing complexity and scope of regulatory requirements, it is now essential to ensure that market surveillance across the EU is not only effective and risk-based, but also fast, predictable, and aligned with industry realities. This is key not only for product safety, but also for maintaining confidence in environmental compliance mechanisms.

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