

Position Paper on the possible revision of the New Legislative Framework

# Making the NLF future-proof: Combining protection objectives, trust and competitiveness



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The TÜV Association welcomes the debate initiated by the European Parliament on the future of the New Legislative Framework (NLF). With its upcoming own-initiative report, the Parliament is putting the review of the existing regulatory architecture for the placing of products on the EU Single Market on the political agenda. The current discussion provides the basis for systematically rethinking the NLF - in terms of better regulation, stronger protection objectives and greater innovative capacity.

This position paper is intended as a contribution to this process. It outlines basic principles and modification approaches for a modern, risk-based and digitally compatible NLF. The TÜV Association is particularly in favour of retaining the variety of modules, greater harmonisation in accreditation practices, the risk-based application of independent conformity assessment and the integration of new tools such as a module on validation, as well as the uniform anchoring of digital product passports within the NLF. The existing NLF Decision 768/2008/EC should be updated in order to maintain it as a coherent, flexibly usable toolbox for future legislation while adapting the Accreditation Regulation (EC) 765/2008 accordingly.

### Executive Summary

The New Legislative Framework (NLF) as the foundation of European product legislation with its well-established basic principles must be preserved in any upcoming revision and at the same time be further updated. The TÜV Association advocates for:

- › The retention of a horizontal NLF Decision as regulatory toolbox for future legislation
- › A consistent focus on achieving protection objectives - instead of deregulation at any cost
- › A risk-based conformity assessment with an appropriate depth of assessment - no de facto prioritisation of a module
- › The inclusion of a new Module V for the independent validation and verification of product claims
- › The assurance of an EU-wide uniform accreditation practice
- › The inclusion of provisions for product passports in the NLF
- › The digitalisation of administrative processes and one-stop shop structures for a smart NLF implementation

## Good regulation as the foundation for an efficient Single Market

The regulation of European products and markets is not an end in itself, but a central element of regulatory responsibility. An effective, rule-of-law-based and coherent regulation ensures that essential protection objectives such as product safety, health, environmental and consumer protection are reliably ensured at a high level. At the same time, it creates trust in markets, paves the way for fair competition and enables innovation. In the view of the TÜV Association, the current debate on reducing bureaucracy and boosting competitiveness must therefore not come at the expense of these protection objectives.

The discourse on reforming the NLF comes at a time when political and economic actors are increasingly questioning the efficiency of the European regulatory model. Numerous political initiatives prioritise easing the burden for businesses by reducing reporting obligations and administrative requirements as primary objective. The recently published Draghi report on EU competitiveness also calls for regulatory processes to be more flexible and innovation-friendly. In the view of the TÜV Association, this is legitimate – but not sufficient.

Good regulation is not an obstacle to growth. On the contrary: It is the prerequisite for sustainable economic development. It ensures planning security, reliable market rules and equal conditions of competition – both within the EU and in international trade. The ambition to reduce bureaucracy must therefore not lead to a generalised criticism of the existing regulatory architecture. Rather, it is important to improve the quality and practicability of legal requirements – without jeopardising the level of protection.

The experience of recent years shows that deficits are not primarily the result of overregulation, but often of unsystematic, politically motivated or insufficiently evidence-based policy-making. The principles of better regulation – clarity, coherence, evidence, participation and transparency – are not applied consistently enough. The New Legislative Framework also suffers from divergent national interpretations and a lack of harmonisation in its implementation – for example in the area of accreditation. In addition, European legislators have in some cases deviated from the basic principles of the NLF and taken special sectoral approaches. This threatens to undermine the – by itself – coherent system of the NLF.

Regulatory change must above all focus on quality and not merely on burden reduction. A 'lege artis' legislation starts with a clear understanding of its purpose: As a tool for enforcing democratically legitimised protection interests. The quality of legislation determines the effectiveness of and trust in European policy.

The aim of a modern NLF must therefore be a smart and targeted legislation: Clearly and unambiguously formulated, well-structured and coherent in its application. This includes ensuring that regulatory requirements are developed in a practice-oriented manner, without making blanket cutbacks in terms of material or assessment depth. The EU does not need a regulatory chainsaw, but a precise and balanced regulatory toolbox – with the aim of ensuring a strong, reliable and innovation-friendly Single Market legislation. This also forms the basis for ambitious trade agreements with other economic partners. That is what the NLF stands for.

## No blanket special provisions for SMEs – safety knows no company size

The European Union attributes particular importance to small and medium-sized enterprises (SMEs) and is committed to their competitiveness. This objective is reflected in the 'Think Small First Principle' and in the SME test for new legislation. The TÜV Association also supports SME-friendly legislation – but not at the expense of product safety, consumer protection or fair market conditions.

In the view of the TÜV Association, essential safety requirements must apply equally to all market players – regardless of their size. The safety of a product or service must not be jeopardised because the manufacturer or provider is a small company. Consumers have a legitimate interest in expecting all products to comply with high safety standards consistently. The principle of equal treatment under EU law also precludes unequal treatment unless it is proportionate and objectively justified.

Regulatory relief for SMEs should therefore be limited to administrative simplifications or longer transition periods, but not to the material level of protection. The rule that 'safety knows no company size' must also apply without restriction in the context of a revised NLF.

Regulatory sandbox approaches, which give companies temporary flexibility with regard to regulatory requirements, can be innovation-friendly, but must not lead to a de facto dismantling of applicable safety standards – in particular not permanently. Safety and consumer protection must not be put at risk. Voluntary assessments by independent third parties within the sandbox, such as the inspection of prototypes, the validation of plans or the verification of starting conditions, can provide support in this regard. Important safety and quality aspects can thereby be integrated into the development process at an early stage without hampering innovation.

## Considering implementation from the outset – clear responsibilities and greater efficiency

The effectiveness of European product legislation depends significantly on its practical implementation in the Member States. An NLF revision must therefore also take a closer look at the reality of implementation. Already today, it is clear that good legislation often fails due to complex, fragmented or unclear administrative structures and inconsistent administrative practices in EU Member States – with negative consequences for the effectiveness of Union law.

A central aspect is the clear and coherent assignment of responsibilities. In the course of the national implementation/transposition of the NLF regulations and directives, there are recurring cases of multiple official responsibilities in the context of accreditation and notification procedures for conformity assessment bodies. These structural redundancies not only hamper the efficiency of the procedures, but also lead to time delays, which can result in considerable competitive disadvantages for both the notified bodies and the affected companies in EU Member States.

In addition, some Member States do not ensure that the relevant structures (expertise, personnel, etc.) are made available to the competent authorities in good time before the directives and regulations enter into

force. This leads to competitive disadvantages for the notified bodies and their customers.

Therefore, the TÜV Association is in favour of defining clearer requirements for structures and timelines within the framework of the NLF. This helps to avoid overlaps and duplicate official controls at Member State level (one-stop shop principle) and to ensure the availability of official structures (for accreditation and notification) by a set deadline.

### Digitalisation update for the NLF

A modern regulatory framework such as the NLF must not only authorise digital processes in administration, but actively promote them. Digitalisation offers enormous opportunities to make procedures more efficient, transparent and easier to plan for all parties involved – from the notification process and market surveillance to the submission of evidence by notified bodies.

The TÜV Association is in favour of anchoring the digital dimension more firmly as a cross-sectional task in the NLF revision. This includes, in particular, the development of a European interoperable digital one-stop-shop approach for authorities that enables the centralised digital handling of administrative processes for the implementation of sectoral product legislation. The aim is to establish standardised administrative procedures with a high degree of predictability and transparency.

The use of modern technologies - including AI-based support for document checks and process management - can also contribute to quality assurance without challenging the ultimate responsibility of authorities.

A digitally enhanced NLF strengthens the efficiency of the administration, promotes consistent procedures, increases the acceptance of regulatory processes – and ultimately improves the quality of Europe as a business location.

### Maintaining the foundations, renewing the toolbox – further development of the NLF Decision 768/2008/EC

The principle that the same must be regulated in the same way already applied when the NLF was reformed in 2008. The aim was to harmonise all horizontally applicable requirements, that should be formulated identically in sectoral directives and regulations, within Decision No. 768/2008/EC. This approach has in principle proved its worth and must be retained. It promotes coherence, legal clarity and a systematic application of the New Legislative Framework in a wide range of product areas. A standardised and horizontal core of legislation not only prevents duplication and contradictions, but also reduces the Member States' room for interpretation.

The potential revision offers the opportunity to extend this principle to other subject areas – such as digital information obligations, sustainability aspects or the handling of software updates and AI components. The same applies here: What is equally relevant in all product sectors should be placed in front of the bracket and regulated in the horizontal part of the NLF.

In the context of a potential revision, various approaches to reform are now being discussed – including the conversion of the Decision into a legally binding regulation or an adaptation of all sectoral directives and regulations by means of a so-called omnibus package. The TÜV Association believes that a targeted further development of the existing Decision is the most appropriate approach. An updated Decision would make it possible to preserve the established core structures of the NLF and at the same time adapt them in a targeted manner – as was the case at the time of the major reform in 2008.

The strength of the Decision lies in its function as a regulatory toolbox: It offers standardised reference provisions for definitions, obligations for economic operators and conformity assessment procedures, which sector-specific legislation can utilise in a flexible manner. Other regulatory areas – such as homologation in the vehicle sector – could be based on this without having to adopt the entire system<sup>1</sup>. This flexibility would be lost with a rigid regulation. At the same time, the Decision also remains of central importance with regard to future regulatory projects: As a horizontal reference, it ensures consistency and system coherence across product groups. Ultimately, the European legislator, as a democratically legitimised policymaker, must be free to decide whether and to what extent it uses which reference provisions.

Therefore, the TÜV Association is in favour of a two-stage approach: In the first instance, the targeted updating of the NLF Decision, followed by a coordinated adaptation of sector-specific directives and regulations by means of an omnibus procedure. This approach combines system adherence with necessary further development and is therefore suitable for transforming the NLF into the next generation of regulatory requirements.

## Harmonisation of the European accreditation framework

The instrument of accreditation is a central pillar of the European quality assurance infrastructure. It guarantees the technical competence, independence and reliability of conformity assessment bodies and thus contributes significantly to the credibility of testing and certification bodies and to the procedures they apply. Their function as a confidence-building instrument is thus directly linked to the free movement of goods and the smooth functioning of the Single Market.

In order to achieve the common goal of a consistent and reliable European accreditation system, a consistent alignment with uniform European and international standards is required. The current ability for national interpretations of the relevant accreditation standards harbours the risk of diverging requirements within the Union. This can result in market distortions, hinder the international comparability of conformity assessments and thus undermine trust in and acceptance of certificates. At the same time, it must be ensured that the established European accreditation system is coherent with the international accreditation system to avoid hampering the cross-border movement of goods.

<sup>1</sup> See also COM/2016/031 final – Explanatory Memorandum: “3.3 Proportionality principle: (...) The measures proposed to reinforce and further harmonise the implementation of the type-approval procedures are based on the agreed principles laid down in the common framework for the marketing of products, and on the reference provisions for Union harmonisation legislation for products as laid down in Annex I of Decision No 768/2008/EC. Where necessary and justified, these provisions have been adapted to the specificities of the automotive sector, in particular with the view to recognise the existence of an already well-established type-approval framework and to ensure full coherence with this framework.

A central objective of the NLF revision should therefore be the legally binding establishment of a more harmonised European accreditation framework. Regulation (EC) No. 765/2008 should be revised in order to ensure a harmonised interpretation and application of the accreditation requirements and to rule out national solo efforts (in particular gold-plating). In this context, it should be examined whether the establishment of a European Accreditation Agency could be a suitable solution to further strengthen coherence, transparency and efficiency of the system.

In addition, the role of advisory bodies at European level should be strengthened on a mandatory basis in order to ensure a balanced and participatory refinement of legislation. A legally guaranteed voice of all relevant stakeholders helps to ensure the quality and acceptance of accreditation practices in the long term.

Finally, the TÜV Association recommends that the current national accreditation practices should be evaluated in terms of their efficiency and accuracy as part of a bureaucratic review. In particular, it should be examined whether these practices deviate from European provisions, whether the stipulated requirements are proportionate and whether they impose unnecessary burdens for companies or conformity assessment bodies.

A consistent European approach to accreditation practice is not a matter of detail – it is a prerequisite for a functioning level-playing-field and for a regulatory environment that ensures safety, trust and economic efficiency alike.

### Conformity assessment in the NLF - risk-based and modular

Conformity assessment is a central element of the New Legislative Framework and serves to determine whether products fulfil the applicable safety, health, environmental and consumer protection requirements. It is therefore a crucial instrument for safeguarding the protection objectives and maintaining a level-playing-field for market players and thus for the functioning of the Single Market. The modularity of conformity assessment in the NLF allows different ways of demonstrating conformity depending on the risk profile of a product. This flexibility has proved its worth and should be maintained in the course of a revision.

In practice, it can increasingly be observed that Module A (internal production control) is being proposed as (politically) preferred solution – due to the assumed reduction in bureaucracy. The TÜV Association warns that this preference could lead to a de facto prioritisation of this module, disregarding the actual risk profile of the product. Such a development would contradict the risk-based approach of the NLF and jeopardise the level of protection.

A NLF revision must therefore ensure that the legislator remains free to select the appropriate conformity assessment procedure to be applied – guided solely by the risk posed by the product. There must be no implicit or explicit preferences in favour of individual modules. The decision for a certain module must always be the result of a risk-based assessment in the light of the protection objectives – not dominated by political or administrative considerations.



'Protection objectives first' means specifically: The conformity assessment procedure to be applied must be determined solely on the basis of the specific protection objective to be safeguarded. If life, limb, physical integrity, the environment or equivalent protection objectives could be endangered by a non-compliant product, a conformity assessment procedure involving a notified body must be chosen. With this in mind, specific principles for a risk-based module selection should be established as part of the NLF revision. Challenges to functional safety, software and cybersecurity aspects must be included in the risk-based assessment.

A modern, risk-based system of conformity assessment is not a barrier to innovation – on the contrary: It provides planning security, strengthens confidence in new technologies and enables safe and fair market access.

### New Module V - validation and verification of product claims

With advancing digitalisation, functional developments and changing product functions during the life cycle, information reflecting a dynamic situation and product-specific claims are becoming increasingly important. More and more frequently, relevant information on performance, environmental compatibility or safety are based on manufacturer declarations – which change over time or through updates. In such cases, traditional assessment methods are often not sufficient making new assessments throughout the product life cycle necessary.

The conformity assessment methods of validation and verification enable the traceable and reliable assessment of statements on product performance or environmental properties – e.g. in the case of digital functions, software updates or carbon footprints. This makes it possible to demonstrate that a declared characteristic is correct and reliable at the time of the statement.

With this in mind, the TÜV Association recommends introducing a new 'Module V' in the NLF. This new conformity assessment procedure should include validation and verification and be based on the ISO/IEC 17029 standard 'Conformity assessment - General principles and requirements for validation and verification bodies'. The aim is to independently assess dynamic, declarative or promised product characteristics in particular. This additional modular component in the NLF represents a much-needed addition to the existing risk-based modules and would increase the adaptability of European product legislation.

### Digital Product Passports – maximise potential, increase transparency

The Digital Product Passport (DPP) is becoming increasingly important as a prospective instrument of regulatory transparency and traceability. It is intended to gather information on product and component origin, material statements, ingredients and, if applicable, chemical substances, but also information on reparability, spare parts or proper disposal of a product, and keep it up to date throughout the product's entire life cycle. The DPP therefore harbours great potential for making regulatory requirements visible and comprehensible – for consumers, market surveillance authorities and other economic operators. However, it is not suitable as a replacement for conformity assessments of products.



Digital Product Passports will be effective transparency instruments in the EU Single Market if their sector-specific designs are as coherent, comparable and compatible as possible – regardless of whether they relate to batteries, toys or construction products. Standardised terminology, data structures and validation requirements promote interoperable solutions and ensure regulatory coherence and legal certainty. In order to create a consistent European framework for Digital Product Passports, horizontal minimum requirements for the DPP should be included in the NLF Decision. A NLF revision offers the opportunity to establish the necessary horizontal principles for this.

In order for the Digital Product Passports to be fully effective and to ensure their relevance in the Single Market, all parties involved, such as economic operators, authorities and consumers, must be able to trust the reliability and completeness of the data and information stored.

The TÜV Association is therefore in favour of complementing the design of Digital Product Passports with robust validation and verification mechanisms. Only the involvement of independent third parties can ensure that the declared data is actually reliable and conformant – in particular with regard to safety and sustainability-related information.

## Our policy recommendations

### General principles

- The objective must be good regulation – not the blanket reduction of regulatory provisions as an alleged means to reduce bureaucracy. Quality, clarity and comprehensibility of legal requirements that serve protection objectives are crucial, as is their practicable implementation.
- Enforcement in the Member States must be more coherent. This requires: Clear administrative responsibilities, avoidance of duplicate structures and the guaranteed provision of administrative capacities before new legislation enters into force.
- Development of a European interoperable digital one-stop-shop model for authorities enabling the centralised digital handling of administrative processes as regards the implementation of sectoral product legislation.
- SMEs should be systematically relieved, but without compromising safety, health and the environment. Administrative simplifications are a possibility, material exemptions are not.
- The existing NLF Decision 768/2008/EC is to be further complemented in a targeted manner instead of transferring the provisions into a regulation or an isolated omnibus procedure.
- The toolbox function must be maintained so that future legislation can build on it flexibly and coherently.
- Standardised model provisions based on the principle of ‘the same before the brackets’ promote legal clarity and coherence, reduce room for interpretation and strengthen the Single Market

## Accreditation

- The EU Accreditation Regulation (EC) 765/2008 should be revised to ensure more consistent and standardised accreditation practices in all EU Member States in the future and to maintain consistency with the international accreditation system.
- National accreditation practices should be regularly evaluated for compliance with EU requirements, efficiency and proportionality to avoid unnecessary hurdles and gold-plating.
- The establishment of a European Accreditation Agency should be examined.

## Conformity assessment

- The selection of conformity assessment procedures must be strictly risk-based. Politically motivated module preferences must be avoided.
- Specific principles for risk-based module selection should be specified in the NLF – including functional safety, software and cybersecurity aspects.
- A new Module V should be included in the NLF to incorporate dynamic product statements. This module should include validation and verification in accordance with ISO/IEC 17029 and be used for, amongst others, environmental information, digital functions or updates.

## Digital Product Passport

- The Digital Product Passport should be conceived as a transparency instrument for compliance and sustainability information – not as a substitute for independent assessments.
- To ensure its validity, validation and verification mechanisms should be mandatory and carried out by independent third parties.
- NLF Decision 768/2008/EC should define horizontal minimum requirements for the organisation, data structure and interoperability of the Digital Product Passport.

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As TÜV Association, we represent the policy interests of the TÜV assessment organisations and foster the professional exchange between our members. We are committed to the technical safety, digital security and sustainability of products, systems and services. Universally applicable standards, independent assessments and qualified training form the basis. Our goal is to maintain the high level of technical safety, to build trust in our digital world and to preserve our livelihoods. To this end, we are in regular exchanges with policymakers, authorities, the media, companies and consumers.