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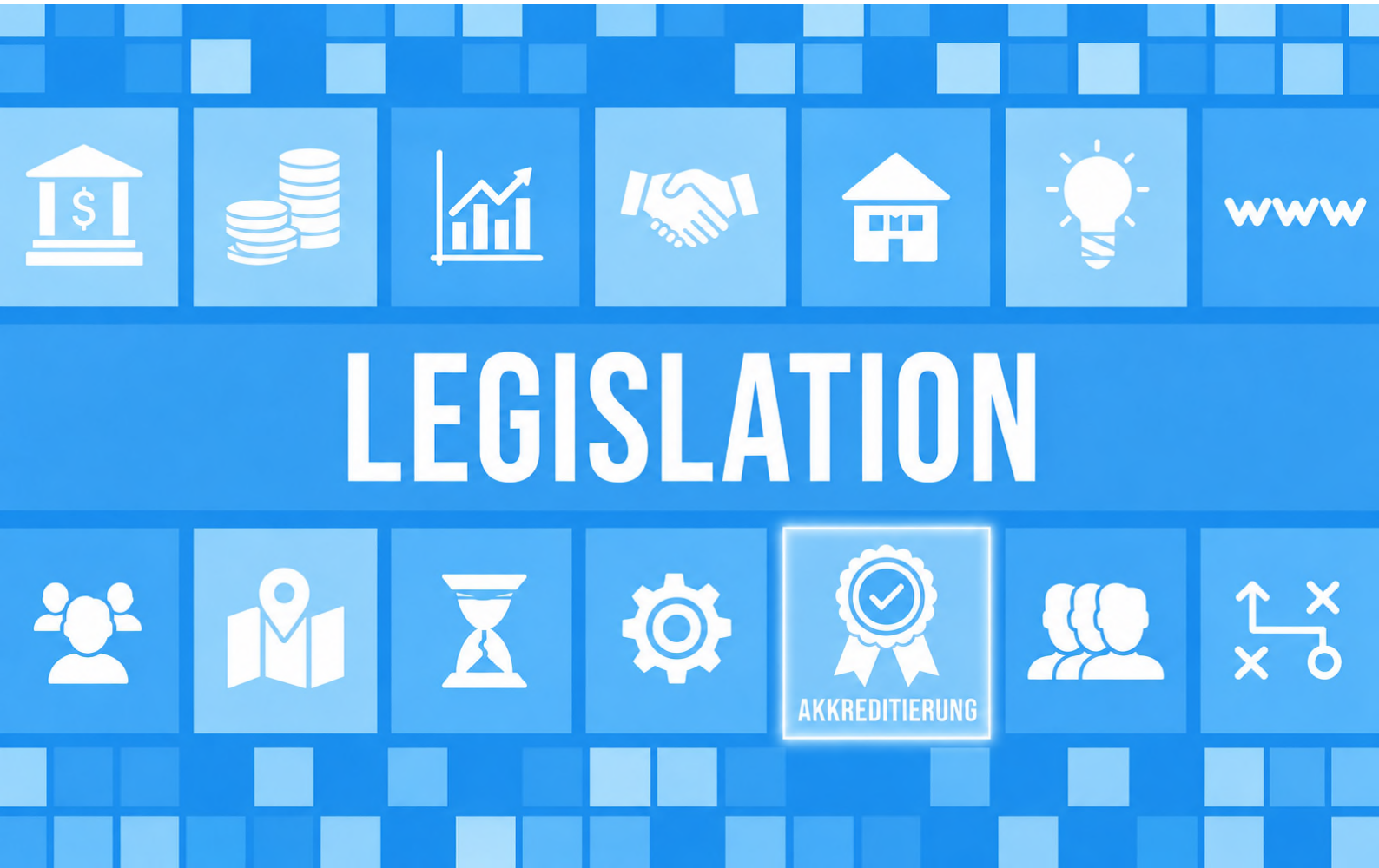
Position Paper on the revision of the New Legislative Framework

Accreditation readiness as a precondition for a functioning EU Single Market



Accreditation readiness as a precondition for a functioning EU Single Market

The TÜV Association welcomes the revision of the New Legislative Framework (NLF) initiated as part of the European Single Market policy. The NLF forms the foundation for safe products, a level playing field and reliable market rules within the EU Single Market. As part of this revision, accreditation – as one of the cornerstones of the European quality infrastructure – should therefore be specifically reviewed and further developed.

Accreditation is a key confidence-building tool of European product legislation. It demonstrates the technical competence, impartiality and reliability of conformity assessment bodies and is therefore a precondition for Notified Bodies to carry out their tasks within the Single Market. Particularly in new regulatory areas – such as the AI Act, the Battery Regulation, sustainability claims or requirements for software and cybersecurity – the timely availability of accreditation services[1] determines whether companies can place their products on the market in a legally compliant manner by the respective date of application of the legal act.

The TÜV Association emphasises that, in order to achieve good regulatory outcomes, national enforcement structures, responsibilities, public officials and digital procedures must be in place in good time. This naturally also applies to accreditation services, as otherwise it would result in competitive disadvantages for Notified Bodies and their customers[2]. The conformity assessment services provided by Notified Bodies, and consequently the placing of products on the EU Single Market, must not be allowed to fail due to a lack of national accreditation readiness.

In order for the provisions to take full effect, accreditation and notification structures must be fully in place by the time EU harmonisation legislation becomes applicable[3]. This requirement is enshrined in EU law in the principle of the practical or full effectiveness of EU law (*effet utile*). Where the application of EU law effectively depends on national preparatory and enforcement structures, these structures must be designed in such a way that the requirements of EU law can actually take full effect from the relevant date of application of the legal act[4].

[1] In this context, 'accreditation service' refers to all accreditation procedures and programmes carried out by an accreditation body for specific conformity assessment activities, legal acts, modules or normative references.
[2] Cf. ISO/IEC 17011:2017: Accreditation bodies must demonstrate their competence, impartiality, and consistent operation. This requirement for reliable performance justifies the expectation that the actual availability of accreditation services is also disclosed in a transparent and reliable manner.
[3] Cf. ISO/IEC 17011:2017: see above, 'operational' in the sense of 'consistent operation'.
[4] See, for example, the judgment of the Court of Justice of the European Union of 19 November 1991 in Joined Cases C-6/90 and C-9/90, Francovich and Bonifaci, ECLI:EU:C:1991:428.

Executive Summary

- Accreditation readiness is an essential precondition for ensuring that EU harmonisation legislation can take practical effect from its date of application.
- National accreditation bodies must at all times publicly disclose, digitally and within a uniform European framework, which accreditation services are currently actually being offered by them.
- An accreditation service may only be listed as currently available if it is not only formally offered, but can be processed and completed within a reasonable timeframe using existing assessment criteria, technical expertise, assessor capacity and decision-making structures.
- If a required accreditation service is not currently available at national level, conformity assessment bodies must be entitled, automatically and without prior consent or a statement of non-availability from the national body, to apply for the service from an accreditation body in another Member State and to complete the procedure there.

Accreditation must not become a market access barrier

If the necessary accreditation readiness is lacking, a structural problem arises within the Single Market. The NLF is based on the interplay of harmonised requirements, harmonised conformity assessment procedures and the mutual recognition of robust evidence. Identical product requirements alone are not sufficient if access to the necessary accreditation and notification procedures in the Member States is of varying speed, varying reliability or, in practice, not guaranteed at all. In such cases, although the same European rules formally apply, the actual market access conditions differ considerably.

This problem is particularly acute in the case of new EU legislation. Notified bodies in Member States where accreditation services are available at an early stage can offer their services in good time, whilst equally qualified bodies in other Member States have to wait. For manufacturers, this means delayed market access, a reduced choice of assessment capacities and de facto distortions of competition. This not only undermines the competitiveness of individual companies, but also the uniform application of European product legislation as a whole.

Small and medium-sized enterprises are particularly affected. Large companies are better able to mitigate delays through their corporate structures, international locations or existing assessment networks. SMEs, on the other hand, are more reliant on predictable and locally available testing and certification services. If accredited Notified Bodies are not available in good time, their search,

coordination and transaction costs rise; at the same time, their access to new regulated markets is delayed.

The bottleneck in the existing system

The current accreditation system under Regulation (EC) No 765/2008 is deliberately based on the principle that each Member State shall, in principle, designate a national accreditation body. Accreditation is not an ordinary service subject to competition, but rather fulfils a public-authority-based function of trust within the quality infrastructure by confirming, in the public interest, the technical competence, impartiality and reliability of a conformity assessment body.

The practical problem lies in the lack of operational safeguards for cases where a national accreditation body is unable to provide a required accreditation service in a timely manner. Article 7(1)(b) of Regulation (EC) No 765/2008 does allow recourse to an accreditation body in another Member State if the competent national accreditation body does not carry out the requested accreditation. In practice, however, it remains unclear when this condition is met, who decides this with binding effect, and whether a conformity assessment body must first wait for its national accreditation body to expressly state that it does not offer a particular accreditation service.

In practice, an accreditation service may also be effectively unavailable: For example, if applications are not yet being accepted, assessment criteria have not yet been finalised, the necessary technical expertise or assessor capacity is lacking, or there are no reliable timetables for carrying out and completing the assessment. Market access for companies is then delayed not because of a lack of competence on the part of the conformity assessment body, but because of a lack of administrative availability of the accreditation procedure at the national accreditation body that is in principle responsible.

Regulation (EC) No 765/2008 already contains vague provisions to address this problem of accreditation services currently being unavailable. Article 4(2) provides that a Member State shall have recourse to the national accreditation body of another Member State if it is not economically viable or sustainable to provide certain accreditation services itself. Article 8(5) requires national accreditation bodies to specify the conformity assessment activities for which they are authorised to provide accreditation. Article 12 sets out information requirements regarding accreditation activities.

However, experience shows that these provisions do not provide a clear, automatic and legally certain mechanism for situations where a necessary accreditation service is required but is not available in the Member State in question in good time.

Ensure transparency about actual availability

As part of the NLF revision, Regulation (EC) No 765/2008 should be specifically strengthened. It is crucial that the actual availability of an accreditation service is transparent, verifiable and comprehensible to all market actors at all times.

At the heart of such a provision should be a transparency obligation requiring national accreditation bodies to publicly disclose, at all times, in digital form and within a uniform European framework, the accreditation services they currently offer. This information should not be provided in general or abstract terms, but should be classified according to the relevant EU harmonisation legislation, conformity assessment procedures or modules, harmonised standards and technical specifications. The current availability of each accreditation service must be clearly indicated.

An accreditation service may only be advertised as currently available if it is not merely offered formally, but can demonstrably be processed and completed within a reliable, transparent and predictable timeframe. This requires that complete and verifiable applications are actually accepted and processed in a timely manner, that the relevant assessment criteria are in place, and that sufficient technical expertise, assessor capacity, internal procedures and decision-making structures are available.

The timeframe for the respective, currently available accreditation procedure should be specified based on published average processing times, clearly defined processing steps and a realistic schedule to be communicated upon receipt of the application. The mere promise to establish a service in the future, or a non-binding declaration of intent by the accreditation body, must not be sufficient.

Legally secure cross-border access where national availability is lacking

If an accreditation service is currently unavailable from the national competent accreditation body, the conformity assessment body should automatically be entitled to apply for the accreditation service, without any further intermediate steps, from an accreditation body in another Member State that currently offers this service and to complete the procedure there. This entitlement

should not be subject to either prior consent or a statement of non-availability from the competent national accreditation body. The involvement of the competent national accreditation body in the cross-border accreditation procedure, whether in an advisory, participatory or observer capacity, is not required in this case.

This mechanism must be clearly distinguished from a tactic approval/authorisation. The conformity assessment body is not deemed accredited without an assessment. The technical assessment remains fully intact. What is accelerated is solely access to an accreditation body within the European system that is actually operational and ready to offer accreditation services. This does not lower the quality of accreditation, but rather strengthens the practical effectiveness of harmonised product legislation across the EU.

In addition, the European Commission should examine how the information published by national accreditation bodies can be presented digitally in a standardised manner through a European register. Such a solution would ensure maximum transparency regarding the accreditation services currently available within the EU Single Market and would make cross-border access – in cases where national services are unavailable – predictable, unbureaucratic and legally secure.

Conclusion: Ensure accreditation readiness, strengthen the Single Market

Accreditation readiness is not a matter of technical detail, but a precondition for a functioning Single Market: Only if accreditation structures are in place in good time can conformity assessment bodies be ready in good time and enable businesses to access the market.

New EU product legislation can only achieve its intended effect in a timely manner if conformity assessment bodies can actually obtain the necessary accreditation in a timely, needs-based and predictable manner. Delays in accreditation lead to delays in notification, reduced assessment capacity within the EU Single Market and unequal market access conditions for Notified Bodies and manufacturers.

The revision of the NLF should therefore be used to add clear rules on transparency on, availability of and access to accreditation services to Regulation (EC) No 765/2008. The aim is not to change the system or lower substantive requirements. The aim is a legally secure mechanism that ensures that a lack of national accreditation readiness does not become a bottleneck for innovation, product safety and market access.

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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.

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