

# ENABLING DIGITALISATION IN THE QUALITY INFRASTRUCTURE

## 10 PRINCIPLES FOR GOOD REGULATION

Recommendations for responsible stakeholders in  
legislation, standardisation and administration

A policy paper by the advisory board of the QI-Digital initiative

Version 1.0

# Background: Legislation as an enabler for digitalisation in the quality infrastructure

A high-performance quality infrastructure (QI) is the basis for the competitiveness of industry and the economy, functioning health, environmental and consumer protection and the success of the green and digital transformation. It is therefore a key success factor for central political goals and programmes.

Digitalisation offers enormous potential for quality assurance and thus for securing competitiveness, increasing productivity and greater transparency along complex production and process chains. The complexity and dynamics of the digital transformation as well as international competitive pressure require a consistent, comprehensive and coordinated digitalisation of QI tools, processes and institutions. However, the development of technical solutions alone is not enough. QI is embedded in a system of regulatory framework conditions, which means that a legal and regulatory framework must also be adapted and developed to enable and promote this digital transformation of QI.

This paper from a working group of the QI Digital Advisory Board presents recommendations for good legislation and "underlying" regulation (e.g. also in standardisation) that supports a transformation towards digital QI. Legislators and standardisers must enable the introduction and use of digital QI tools and procedures. To this end, the following 10 principles should be taken into account in legislative and regulatory practice.

The paper is aimed at national and European legislators, rule-makers, those active in standardisation, specialist politicians and other interested parties from politics, administration, business and society. It also expressly serves as a basis for further practice-oriented development and an invitation to a corresponding dialogue between the stakeholders.

## **What does digitalisation in the quality infrastructure (QI) mean?**

QI ensures trust in information and is based on standardisation, conformity assessment (e.g. testing, calibration, certification), accreditation, metrology and market surveillance, which are continuously "intertwined".

A QI with digital tools, processes and data spaces will improve quality assurance processes in companies and enable the fast, integrated, frictionless provision of quality information across the entire value chain - for all QI stakeholders. With the support of QI-Digital, requirements will in future be automatically checked as machine-understandable standards (SMART standards), results reports will be provided digitally and digital certificates will be transmitted as eAttestation without media discontinuity. Digital data infrastructures such as Quality-X enable the optimisation of data flow and access.

# 10 principles for good standardisation

## General principles and fundamentals

### 1. Naturally accept digital formats

Existing requirements for written form and paper documentation lead to considerable effort, unnecessary consumption of resources and media disruptions that delay and complicate processes. Interoperable standardised digital formats, on the other hand, enable the secure and trustworthy exchange of data without media discontinuity.

- Written form requirements should be withdrawn where possible or digital solutions should be accepted as equivalent.
- Wherever it is deemed necessary to prescribe certain formats, digital formats should be accepted as an alternative (or as a substitute) as equivalent in the medium term.

### 2. Standardise requirements

Companies have to deal with different regulations and requirements for products or processes, which vary unnecessarily depending on the region, sector or function and lead to additional expense and complexity.

- Standardised requirements should be defined for comparable circumstances and also implemented in sectoral regulations.
- Uniform application of laws and rules should be guaranteed in the enforcement of regulation.

## Implement digitalisation well

### 3. Focus on processes and users

The mere transfer of cumbersome and inefficient analogue processes and procedures to digital hardly brings any administrative relief to QI stakeholders and companies in particular. Rather, a genuine, relieving transformation requires fundamental innovations.

- The starting point for digitalisation considerations should always be the application perspective and the (overall) process. Processes should be considered from the end and with a clear focus on the benefits for users.
- As processes can also extend beyond organisational boundaries and areas of responsibility, the entire QI must be taken into account.

### 4. Overcoming silo thinking

Divergent regulations and a lack of coordination along geographical borders between federal states or districts as well as sectoral borders and functional legal areas represent an unnecessary additional effort for companies in the formulation, fulfilment and verification of requirements.

- Cooperation across federal and sectoral levels, areas of competence and responsibilities must be strengthened in order to enable uniform digital procedures and ensure their scalability
- This requires binding requirements, e.g. via state treaties

## **5. Introduce a digital check across the board - consider the potential of digitalisation from the outset**

The introduction of technically possible digital solutions in QI is often hindered by the lack of digital suitability of existing laws and regulations. At the federal level, the digital check initiative has at least provided a remedy for new legislative proposals.

- A digital check for the digital suitability of legislative content is welcomed and should be applied consistently from the start of a new or amended regulatory project in order to consider the potential of digitalisation in the form of "smart regulation" from the outset. This should also apply to rules at federal level as well as to standards and technical regulations. This should also apply to rules at federal level as well as to standards and technical regulations.
- The existing Standards Control Council could be used for this purpose.

## **6. Creating/strengthening capacities and resources**

The QI involves a large number of official players who must work together and in a coordinated manner to shape the digital transformation. Implementation involves countless institutions involved in various functions and sectors at federal, state and municipal level.

- Relevant executive actors and QI institutions should be given the necessary capacities and competences to successfully implement the digital transformation and advise those responsible for setting regulations on the requirements.
- All parties involved must be able to exchange data securely and digitally; if this is not already the case, the necessary infrastructure must be created and resources made available to enable innovation.

## **Enabling innovations**

### **7. Opening up spaces for experimentation**

In order to keep pace with the digital transformation in the economy, an agile approach is needed in the adaptation of the QI-relevant legal framework, which allows innovations for QI to be tested and then quickly implemented in a legally secure manner.

- The opportunities offered by real-world laboratories as test rooms for innovation and regulation (also known as "regulatory sandboxes"; see the Federal Government's Real-World Laboratories Act) should be utilised to a greater extent

## **8. Rethink existing practice, dare to try something new**

QI is based on procedures and processes that have been practised for decades and which are increasingly outgrowing the new requirements of a digitalised application world. For example, rigid inspection deadlines that were once defined could already be converted into status-dependent procedures using digital technologies if the legal framework allowed such innovations.

- This requires more flexibility in achieving and safeguarding protection goals.
- This also includes actively taking up existing digital developments and solutions and implementing them in an unbureaucratic manner.

## **9. Involving interest groups/stakeholders**

In order to enable or accelerate the digital transformation in the regulatory process, the necessary interlinking of specialist topics with digitalisation expertise is often lacking. The lack of an uncomplicated way to be involved in regulatory procedures and provide feedback is a barrier to participation, especially for SMEs.

- Broader and lower-threshold participation opportunities for relevant interest groups in the rulemaking process should be guaranteed and promoted - including through the use of digital options.
- In addition to the technical experts in the area to be regulated, experts with digitalisation knowledge should also be involved.

## **10. Ensure openness to technology**

Successful, goal-oriented digitalisation of QI requires technological freedom and choice, e.g. when labelling with barcodes or QR codes. The aim must be to avoid technological path dependencies (lock-in risks).

- Statutory regulations should refrain from specifying concrete technical and methodological solutions and instead limit themselves to specifying the protection goals to be achieved. The regulatory concept of the NLF can serve as a model (Decision 768/2008/EC).
- At the same time, a secure, standardised exchange of information that can be implemented without hurdles should be ensured (interoperability).

- The technical solutions ("state of the art") should be determined by means of norms and standards.

The principles paper is a document of the QI-Digital Advisory Board and was developed by the Advisory Board's "Regulatory Affairs" focus group.

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This paper is an invitation to dialogue. We are happy to develop it further with you.

We look forward to your suggestions and questions: [info@qi-digital.de](mailto:info@qi-digital.de)

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The **quality infrastructure** (QI) comprises the system of (public and private) organisations together with the policy, the relevant legal and administrative framework and practices required to support and improve the quality, safety and environmental performance of goods, services and processes (INetQI).

## Initiative QI-Digital

Quality Infrastructure Digital (QI-Digital) is a joint initiative of the central actors of the German quality infrastructure: BAM, DAkkS, DIN, DKE and PTB. The initiative is funded by the *Federal Ministry of Economics and Climate Action* (BMWK). Together with partners from industry, it develops practical solutions for a modern, agile and digital quality infrastructure. The aim is to digitalise established quality assurance structures and processes and to demonstrate the potential of how a modern and digital QI can support the green transformation. In this way, it contributes to securing the competitiveness of the German economy in the long term.

[www.qi-digital.de](http://www.qi-digital.de)



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