



**BDI**

The Voice of  
German Industry



## **Position | New Legislative Framework**

BDI's key demands for the area of product regulation in the European single market



## Contents

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<b>Introduction</b> .....	<b>5</b>
<b>Placing German industrial products on the European single market</b> .....	<b>5</b>
<b>German industry's key demands for the further development of NLF</b> .....	<b>6</b>
<b>1. Preserve business-led conformity assessment – no product approval procedures by authorities</b> .....	<b>6</b>
<b>2. Strengthen accreditation system – no unilateral national solutions</b> .....	<b>8</b>
<b>3. Organise effective market surveillance</b> .....	<b>10</b>
<b>4. Stability, coherence and clarity indispensable in the EU rules</b> .....	<b>11</b>
<b>5. Preserve strongpoints of the European Standardisation System</b> .....	<b>12</b>
<b>Summary</b> .....	<b>13</b>
<b>Imprint</b> .....	<b>14</b>



**The NLF is the model of regulation that has made the European single market possible. It is thus a model for success which should be used more extensively and further developed.**

## Introduction

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Germany plays a particular role on an international comparison. There are only a few other highly developed industrialised countries where industry accounts for a high and stable share. This industry generates one quarter of German gross domestic product (GDP). If industrial services are added in, the figure rises to one third of GDP. As the leading organisation of German industry and industrial service providers, BDI speaks for 36 sectoral associations. It represents the interests of more than 100,000 large, medium-sized and small businesses vis-à-vis policy-makers and the public sphere.

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### **Placing German industrial products on the European single market**

Germany has far and away the largest industrial share and generates almost one third of total industrial added value in Europe. It delivers and receives more than 40% of all cross-border inputs for manufacturing industry. Based on a market economy order, the European single market constitutes an indispensable, stable and harmonised economic area in which German companies can market products using a single set of rules. Under the so-called "New Approach", these products must meet requirements, in particular the relevant safety and health requirements offering a high level of protection. The duty to comply with these conformity requirements lies with companies.

Led by the idea of further promoting free market access and improving the placement of compliant products on the single market, in 2008 the European legislator adopted the "New Legislative Framework" (NLF) for the marketing and conformity assessment of products in the European Union. NLF merges the two legislative frameworks already established in 1985 ("New Approach") and 1993 ("Global Approach"), develops them further and hence forms the cornerstone of the European single market for products.

This model of regulation is what has made the single market possible and is thus a model for success which should be used more extensively and further developed.

## German industry's key demands for the further development of NLF

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German industry looks on with concern at current developments at European level in the legislative review and reformulation of product requirements. The parties involved in the policy-making process (European Commission, Member States, European Parliament, etc.) are leaning towards no longer applying the successful NLF with sufficient across-the-board consistency or wanting to agree rules which depart seriously from NLF to the detriment of the system. Examples include the vehicle type approval regulation, the medical products regulation or the construction products regulation. Such proposals for separate solutions for individual product sectors are increasingly being made, in particular as a reaction to exposure of scandals relating to non-compliant products. However, they lack a convincing and logically coherent justification for the proposed system change and do not provide a consistent response to the real causes of non-compliance in products. In other words, under the banner of "reform", they constitute an

overhasty call for a "system change" which would lead de facto to legal inconsistencies and competitive disadvantages. Yet the tried and tested NLF system approach could be durably strengthened through targeted closure of regulatory loopholes and case-by-case sectoral adjustments without frictional losses. In addition, effective market surveillance is necessary.

From the angle of German industry, with a strong position in Europe and on the world market, BDI has identified essential key concerns in the areas of conformity assessment, accreditation, market surveillance, regulatory stability and standardisation with a view to appropriate and efficient product regulation.

In this connection, BDI highlights the following worrying developments in the current policy debate which need to be revisited:

## 1. Preserve business-led conformity assessment – no product approval procedures by authorities

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The numerous directives and regulations applying the principles of the New Approach and NLF specify that relevant products may only be placed on the market with CE marking and associated EC/EU conformity declaration. In this way, manufacturers declare that their products meet the relevant requirements, i.e. that they are compliant. The conformity assessment procedures necessary for this are carried out autonomously by the manufacturers themselves in most cases; there is usually provision for the involvement of an independent testing organisation (“Notified Body”) in the case of products with a particularly high risk potential.

- The manufacturer of the product alone bears responsibility for compliance with the legal requirements. Hence, conformity assessment organised and supported by the private sector is certainly preferable to product approval procedures by the state or authorities. Only in a few exceptional cases do the relevant EU provisions require the manufacturer to call on an outside agency. The involvement of an outside agency is an act of delegation between economic operators governed by private law. This leads to a short time-to-market period as well as to conditions for conformity assessment activities which are geared to the market. German industry is convinced that isolated instances of an enforcement deficit should not be rectified through greater direct state intervention (e.g. official product approval models). In this context, the “fee schedules” for conformity assessment activities

performed by independent third parties and at the same time commissioned exclusively by the authorities as has sometimes been proposed (e.g. most recently for the vehicle type approval regulation) should be strictly rejected. Such stand-alone regulatory routes harm German industry to a considerable extent and should therefore be firmly rejected as a regulatory wrong turning.

- Annex II of decision 768/2008/EC comprises a definitive list of functional, efficient and effective conformity assessment modules. Business calls for strict maintenance of the modules set out there with a view to the necessary consistency and uniformity in the European rules. Policy-makers should refrain from developing new, divergent modules. When modules are selected for conformity assessment, a risk-based approach should be chosen for the conformity assessment procedure to be carried out, in strict compliance with the selection criteria set out in article 4 of decision 768/2008/EC for a particular product.
- Not all existing requirements for CE marking correspond to NLF. Since several requirements for CE marking have to be applied for many products, a consistent approximation of these requirements with NLF is important. Business therefore calls on the European legislator to adapt existing and new product regulation requirements to NLF or to consolidate them. Sectoral divergences should be strictly avoided.

## 2. Strengthen accreditation system – no unilateral national solutions

Internationally and in Europe, accreditation is a system which business actively supports and firmly endorses. Accreditation points are national points entrusted with sovereign tasks which establish the competence of conformity assessment points to perform conformity assessments, at the latter's request. As well as issuing accreditation certificates, under NLF national accreditation points also have the task of monitoring the work of accredited conformity assessment points. Regulation (EC) 765/2008 lays down uniform requirements for accreditation in Europe. International linkage of the accreditation system is ensured via the agreements and institutions European Accreditation, International Laboratory Accreditation Cooperation and International Accreditation Forum. Accordingly, the accreditation system overall offers a consistent, efficient but at the same time completely adequate instrument for establishing the competence of conformity assessment points.

German business expressly advocates for the following points:

- European accreditation regulation 765/2008 must be implemented uniformly in the Member States. This regulation describes the main requirements for how accreditation of conformity assessment points is organised and implemented under the umbrella of NLF. As service providers, conformity assessment points themselves have to meet differentiated requirement standards which describe the state of the art with regard to the organisation and competence of conformity assessment points. The series DIN EN ISO/IEC 17000 forms the standardisation principles for the requirements on conformity assessment points and their accreditation, and as a result serves harmonisation of conformity assessment. Hence, this series of standards makes a decisive contribution to the comparability and recognition of conformity assessment results. To ensure a uniform level of competence, the same standardisation principles should be used in the accreditation process across Europe.
- There must be no national requirements for the nomination of conformity assessment points which go beyond accreditation. Against the background that a nomination of these points by the competent national authorities is specified in accordance with NLF, the nomination procedure should be restricted to an administrative act which is based exclusively and objectively on accreditation in terms of establishing the point's competence. All gold-plating, i.e. official or national nomination requirements for conformity assessment points which go beyond accreditation requirements, should be strictly avoided. Because such requirements would run counter to the idea of uniform Europe-wide transposition/application of the law, lead to unnecessary bureaucratic effort and double assessments, create new single market obstacles through different competence requirements, distort competition and disproportionately burden the economic operators affected. When formulating directives and regulations, the European legislator should therefore work in the direction of ruling out, wherever possible, excessive national tendencies through clear and exhaustive European requirements for the nomination of conformity assessment points and any additional requirements they might wish to impose. The European Commission should oblige the Member States and their competent bodies to accept accreditations as the preferred and adequate means for establishing competence.
- Mutual recognition of accreditations within the European Union must be ensured effectively and durably. In this connection, business calls for the rules put in place by European Accreditation to be formulated in a clearly more practical form and for any national legal special arrangements to be free from contradiction.



**The BDI looks on with concern at current developments at European level in the legislative review and reformulation of product requirements. There is a tendency towards no longer applying the successful NLF 100 % thoroughly and consistently.**

### 3. Organise effective market surveillance

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Good regulation on its own does not ensure compliant products. Meeting the legal requirements is the essential basis for a functioning single market. The person placing the product on the market is responsible for complying with the law. The purpose of state market surveillance is to verify that this actually happens. It should make it possible not only to identify and keep off or remove from the market products which are unsafe or harmful in some other way but also to punish dishonest or criminal players. Only functioning market surveillance can ensure a level playing field. Nothing distorts fair competition more thoroughly than market players who secure an unjustified advantage by marketing non-compliant products.

- Market surveillance within Europe and at its external frontiers is inadequate, in particular outside the area of consumer goods. Business calls for market surveillance authorities to be given better human and financial resources.
- Double work ties up important resources in market surveillance authorities. Industry therefore calls for a better exchange between the authorities, also beyond Member States' borders. A concrete instrument for this is use of the existing databases RAPEX and ICSMS. Business also calls for a merger of the two databases to be explored. In industry's view, deficits in market surveillance cannot be solved through the introduction of new databases. Only if there is a clear delimitation of responsibilities and competences beyond the borders of EU Member States are authorities sufficiently in a position to request the necessary documentation from manufacturers for verification.
- In the eyes of business, more effective controls must be implemented at the EU's external frontiers in order to prevent an unwanted discrimination against European manufacturers as compared with their non-European competitors in the European single market as well as the associated distortions of competition.
- Functioning market surveillance also benefits from more effective cooperation between industry and authorities. Business would like to see development of such an exchange, for instance in the framework of working groups involving all relevant players. In this way, market surveillance authorities can take advantage of manufacturers' and independent outside agencies' technical knowledge and would be in a better position to identify non-compliant products on the market and set appropriate priorities for market surveillance.
- It is important to work towards a specification and hence harmonisation of the frequency of random inspections by market surveillance authorities which is binding at European level. Thus, the concrete perimeter of market surveillance activities and the frequency of checks should in future no longer be left exclusively to the discretion of the individual EU Member States. The concept of "appropriate" as applied to checks inter alia in regulation 765/2008 on accreditation and market surveillance (cf. its article 19 paragraph 1) as well as in the current draft regulation in the framework of the so-called product safety and market surveillance package is far too unspecific and as a result leads to unacceptable discrepancies in market surveillance practice within the EU due to the concomitant wide leeway for interpretation and transposition. A more specific transposition as in the provisions of the German product safety law (Produktsicherheitsgesetz – ProdSG) is the right approach. Article 26 ProdSG provides for a "guide value of 0.5 checks per 1,000 inhabitants and per year". Hence, the European legal requirements for market surveillance should be supplemented by a quantitative requirement specifying the necessary number of checks.
- BDI points out that there has been a new economic operator on the market for several years: the fulfilment centre. Fulfilment covers all activities relating to delivery to the customer and execution of the other contractual obligations after the contract has been concluded. Fulfilment tasks are often performed by specialist logistics service providers. The concept of fulfilment usually comes into play in connection with online commerce. In this case, the logistics service provider takes over all those tasks which follow the activation of an online order. Formally, this player does not meet all the criteria set out in EC regulation 765/2008 for an "economic operator" within the supply chain. As a result, the market surveillance authority can only act against it to a limited extent. Industry sees here a need for amendment to the effect that market surveillance authorities can take measures against fulfilment centres in the same way as they can against classical economic operators in accordance with EC regulation 765/2008.
- A new but above all more ambitious legislative proposal is needed in order further to improve the provisions on market surveillance and consolidate harmonised rules applicable across Europe. The demands set out in this BDI paper should be taken into account in the course of this exercise.

## 4. Stability, coherence and clarity indispensable in the EU rules

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A stable European regulatory framework is important not only for industry but also for market surveillance authorities. To secure this, clear formulation and adequate consideration of all areas of applicability is indispensable. In industry's view, the principle of "quality before speed" should apply for the formulation of regulations and directives. This presupposes that all interested circles are adequately involved in the debate.

- BDI calls on policy-makers to act in accordance with the principle of "quality before speed" for the formulation of directives and regulations. This presupposes that the European Commission involves all the main players as early and as extensively as possible in the preparation of legislative proposals. Only in this way can it be ensured that all essential areas of applicability are adequately discussed and then dealt with in a logical and balanced way at regulatory level. Business would therefore like both its own representatives and representatives of the Member States and market surveillance authorities to be involved as early as possible in EU product regulation so that it can contribute to the goal of better regulation with its commitment and high level of professional and specialist competence. For instance, this can be organised via permanent or ad hoc working groups.
- A good regulatory framework is a stable regulatory framework. An element of this is that the legislator is restricted to the fundamental requirements and that these are unambiguously formulated. The legal framework for product regulation in Europe must be coherent and uniform, and offer economic operators a stable and dependable basis for efficient business activity. A careful, technically substantiated impact assessment which is logical and comprehensible to the parties concerned should be self-evident whenever new regulation is envisaged or existing legislation is being amended. Business sees a need for action here.
- The European Commission's guidelines for application of the directives broadly constitute a valuable tool. At the same time, they highlight a weakness in the underlying legislation which is often insufficiently clearly formulated for practical application or has proved in retrospect to be inadequately thought through. However, business is concerned to note the tendency whereby "rulings" which go beyond the actual European legal acquis or even modify it are implemented in effect through the back door in one case or another, inter alia through guidelines, recommendations or FAQs issued by the Member States and their authorities or even by the European Commission. The same also applies for internal documents within the Commission and/or administrations which often subsequently acquire a binding effect in their interpretation by the executive for economic operators. When single market provisions are being drafted or reviewed, greater attention should therefore be paid to removing or avoiding, to the greatest extent possible, linguistic ambiguities and any margins for interpretation of the legal provisions with a view to uniform practice in application across Europe. In addition, when the legal parameters of the conformity assessment procedure are decided, the corresponding requirements concerning the duties of economic stakeholders should be framed as clearly as possible and international standards should be taken into account. By following this recommendation, a large number of "clarifying" follow-up documents in the form of Commission recommendations, FAQs, interpretation papers and the like which do not add to legal certainty can be avoided.

## 5. Preserve strongpoints of the European Standardisation System

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The European standardisation system is internationally competitive. In the last analysis, standardisation is driven and supported by business. Because it is primarily economic stakeholders who ensure that the right content is incorporated in standards at the right time. The international standards rulebook via ISO and IEC is broadly consistent and enjoys a high level of acceptance. This, too, is an important component of the strong position of German business on the world market.

BDI increasingly observes unfortunate situations in NLF-related standardisation:

- The competitiveness of German business is based in part on the fact that it has been an early mover in the harmonisation of material goods via standardisation. This harmonisation leads to product requirements which are uniform across Europe and around the world. Industry and parties involved in the standardisation process have shown that they themselves are best placed to assess what content deserves to be standardised and at what speed. Against this background, BDI speaks out clearly against the increasing political influence on standardisation content. In the framework of NLF, the European Commission has the possibility to award orders to CEN/CENELEC via standardisation mandates. Economic stakeholders can often assess whether and with what content this mandate can be filled better than the Commission. From the standpoint of industry, a stronger return to a framework mandate is desirable.
- The core area of standardisation is product standardisation in the framework of NLF. However, alongside this, non-technical themes are becoming increasingly important. In this connection, industry calls for limited resources – also in business – not to be overstretched.
- Even if the European Commission and national governments have an interest in a certain standardisation content and beyond this also want to strengthen the competitiveness of business, BDI urges that the standardisation system should continue to be financed essentially by business. In addition, standardisation must be market-oriented and organised by the private sector.
- The recent ECJ ruling on harmonised standards in the area of the construction products directive (C-613/14) must not lead to the consensus prevailing among stakeholders in European standardisation about its mode of functioning being repudiated.

## Summary

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For German industry, the European single market constitutes an indispensable, stable and harmonised economic area in which companies can market products applying uniform rules. Under the so-called NLF, products must meet the relevant safety and health requirements offering a high level of protection. The duty to comply with these conformity requirements lies with companies.

BDI is concerned to note that players in the European policy-making process are leaning towards no longer applying the successful NLF with sufficient across-the-board consistency or wanting to agree rules which depart seriously from NLF to the detriment of the system. Against this background, BDI has identified essential key concerns in the areas of conformity assessment, accreditation, market surveillance, regulatory stability

and standardisation with a view to appropriate and efficient product regulation:

- Preserve business-led conformity assessment – no product approval procedures by authorities
- Strengthen accreditation system – no unilateral national solutions
- Organise efficient market surveillance
- Ensure stability, coherence and clarity in the European rules on product regulation
- Market-oriented European standardisation organised and financed by the private sector – no political influences

## Imprint

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