Verband der TÜV e. V.

Upgrade the European Single Market
with compliant products and services

TÜV®

TWELVE VDTÜV RECOMMENDATIONS FOR THE EUROPEAN SINGLE MARKET

1. Uniform requirements for products and services as well as their conformity as key factors for a well-functioning internal market.

2. Better health protection and safety of European citizens by a higher level of conformity in the market.

3. Effective market surveillance for Europe - eliminate systemic differences.

4. Raise uniformly the intensity of market surveillance by concrete and strict legal requirements throughout Europe.

5. Increase prevention by product testing prior to their marketing.

6. Effective "Product Compliance Initiative" by independent third party testing.

7. Enhance efficiency and substitute responsibilities of the public sector with the help of independent testing funded by cause.

8. Concentrate market surveillance measures on self-proclaimed manufacturer's products (SDoc).

9. Further strengthen the principle of mutual recognition by the presumption of conformity to independently tested products.

10. Market-driven, privately organised and financed standardization.

11. Respond to increasing hazard potential of established and new product groups.

12. Design and apply consistently the "New Approach" as a coherent and internationally competitive regulatory framework for the marketing of products and services.

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The European Single Market is based on common legislation harmonised across Europe on the one hand and on trust between economic operators in the course of mutual recognition of national regulations on the other hand.

Most recently, the rules for both methods to place products on the market were revised in the so-called 2008 Goods Package. This includes:

- Regulation No. 764/2008/EC on procedures for the application of national technical guidelines for products that have lawfully been placed on the market in another member state
- Regulation 765/2008/EC on rules for accreditation and market surveillance related to the marketing of products
- Resolution No. 768/2008/EC on a common regulatory framework for the marketing of products

Against this background, the Association of Technical Inspection Agencies (VdTÜV) welcomes the initiative of the European Commission (EC) to review the regulatory framework for the European Single Market.

The VdTÜV comments on the communication on "Upgrading the Single Market: more opportunities for people and business" from 28/10/2015 as follows:

Key factors – Uniform requirements for products and services and their conformity

International trade continues to grow and value creation chain networks extend all over the globe. The European consumers are benefiting from a growing range of products, at the same time they need to be able to trust that the products are safe. However, this is not the case all too often. The EC logically takes up the problem of non-compliant products in the European Single Market in its communication, see page 18:

"In addition, the increasing presence on the market of products that are not compliant with EU rules puts law-abiding operators at a disadvantage and endangers consumers."[1]

The Commission justifies the need for action with alarming numbers with respect to a "high number of non-compliant products"[2] in the accompanying staff working document (SWD). According to data material provided by 16 European Member States, 32 percent of toys, 55 percent of construction products, 30 percent of electrical equipment (low voltage devices) and 40 percent of the personal protective equipment was not compliant. Furthermore, the Commission cited in this context the results of an IFIA study[3] (International Federation of Inspection Agencies) from the year 2014 as follows:

"A study by the Consumer and Industrial Products Committee (No. 39) of IFIA on electrical products for household use performed in 2014 shows that there is a significant number of non-compliant products with safety issues imported from the outside the EU, which circulate within the Single Market."[4]

Conformity with the requirements on products and services is the key for a smooth functioning of the European Single Market as well as for the protection of the health and safety of European citizens. In addition, only flawless

products are able to compete in international trade. Therefore, the benefits of the single market can only fully unfold for all economic operators if the conformity of the products traded in the single market increases significantly and sustainably. To achieve this objective, the Commission announced in its communication the improvement of market surveillance by the European Member States on the one hand, as well as an "an initiative to strengthen product compliance"[5] on the other hand.

Effective market surveillance for Europe[6]

According to the communication, the Commission wants to "consolidate the existing framework for market surveillance activities; encourage joint actions by market surveillance authorities from several Member States; improve the exchange of information and promote the coordination of market surveillance programmes".[7]

The European legislator has transferred the identification of non-compliant products on the market to national market surveillance authorities of the European Member States. They therefore have to exercise the necessary protection function for the citizens of the European Union. The measures announced by the EC are heading in the right direction, but fall too short because the need for action is significant, as the Commission also notes in their SWD: "However, market surveillance does not operate effectively in the EU."[8]

Market surveillance in Europe shows weaknesses

Market surveillance in Europe currently shows serious weaknesses in practice, especially as it is performed with varying resources and fragmented intensity by the authorities in the individual member states. It must, therefore, be urgently improved and brought up to a consistently high level in Europe, as strikingly shown, amongst other things, in the latest RAPEX report (RAPEX - Rapid Exchange of Information System - rapid alert system for dangerous consumer products) from 2015.

The report stated that France, with 64 million residents, had approximately the same number of reports of dangerous products (163) as Cyprus (151) – a country with a population of 880,000. Similarly, Italy, a country with 61 million inhabitants, has only 1/8 of the number of reports of Hungary with 9 million inhabitants. These significant systemic differences between the European Member States in market surveillance practice jeopardize their proposed functionality and must therefore be eliminated urgently.

Market surveillance needs stricter legal regulations

The regulation proposed by the EC early 2013 on market surveillance goes in the right direction and must be adopted finally. It is intended to create a modern, single legal framework by consolidating and modernising existing parallel regulations. In addition, the national authorities must be equipped with sufficient budgetary resources to ensure harmonised market surveillance with the necessary volume and efficiency.

The concrete scope of market surveillance activities and the frequency of checks should, however, no longer be left solely to the discretion of the respective European Member States in the future. Rightly, the Commission notes in

this respect: “Furthermore, in order to have a real impact on businesses’ willingness to comply, the overall number of product checks need to be sufficiently high.”[9]

The term of “adequacy” of samples found, for example, in Regulation 765/2008 on accreditation and market surveillance (cf. article 19 (1)) as well as in the current draft of the regulation in the context of the product safety and market surveillance package is far too vague and, as a result of the associated room for manoeuvre in terms of design and implementation, leads to unacceptable discrepancies in market surveillance practice within the European Union. The actual implementation of the current provisions in the German Product Safety Act (ProdSG) is the right approach from the perspective of the VdTÜV. Article 26 ProdSG provides for a “benchmark of 0.5 samples per 1,000 citizens per year”[10]. Specific size regulations on the required number of samples should be included in the new European legislation.

Product compliance initiative through independent third-party testing

According to its communication, the EC “will therefore introduce an initiative to strengthen product compliance by providing the right incentives to economic operators, intensifying compliance checks and promoting closer cross-border cooperation among enforcement authorities, including through cooperation with customs authorities”[11].

The VdTÜV supports this objective expressly, but this proposal is also in need of further specification. The sectors with the highest proportion of non-compliant products referred to by the Commission concern in particular the products marketed almost exclusively on the basis of a pure manufacturer’s self-declaration in the harmonised area of regulation. This means that the manufacturer designs and manufactures its products in accordance with harmonised standards. It is therefore presumed that the products are compliant. On this basis, he declares that the legal requirements are fulfilled by affixing the CE marking. Yet no one checks this statement of conformity!

Rather, the market surveillance authorities should subsequently find the non-compliant products on the market and identify false declarations of conformity from the economic operators. However, the “black sheep” among them, who do not follow the rules and in particular lead to massive distortions of competition in the European market, cannot be moved to change their behaviour “by strengthening market surveillance and providing the right incentives to economic operators”[12].

In addition, the advised possibility of the Commission “to demonstrate product compliance to competent authorities, and potentially also consumers, by digital means (e-compliance)[13], means an apparent appreciation of the pure manufacturer’s self-declaration, but essentially remains unchanged and ultimately leads to a false sense of security.

The experience of recent years shows that the conformity assessment on European level would increasingly have to be developed further into an actual check of the product itself (through type examination connected with production monitoring and unannounced controls), to achieve a higher level of product conformity in the market.

There is also an urgent need for a reversal towards a preventive approach, in which products will increasingly be tested reliably by independent testing organisations according to their conformity before their marketing.

Independent testing is efficient and supports the public sector

Regarding the very limited budgetary resources of the member states, expansion of market surveillance will only be possible to a very limited extent in future. In the meantime, however, the necessary field of action continues to expand. Since the Product Safety Directive was ratified in 1995, global trade has noticeably exploded. Whilst worldwide exports were still at the level of 5,171 billion US Dollars in 1995, they already amounted to 15,229 billion US Dollars in 2010.[14] In principle, official intervention is useful and necessary after products have entered the market, but in future will by no means be sufficient in order to ensure that only conforming and therefore safe products reach consumers in all areas.

In this context, independent testing of products at the beginning of the value creation process or, in other words, before products enter the market, represents a useful and necessary complement to market surveillance activities by national authorities. With the independent testing by third parties, unsafe products are then identified early and therefore do not even enter the market. In view of the limited resources of the market surveillance authorities, this preventive approach is efficient, economic and sustainable.

Example the United States of America: Conformity of products through independent testing

In the USA, consumer products are generally subject to mandatory independent testing and therefore commonly conforming. Current studies by IFIA (The International Federation of Inspection Agencies) and CEOC (Confederation of Inspection and Certification Organisations International)[15] on electrical consumer goods show that products being put into circulation on the mere basis of a manufacturer's Self-Declaration of Conformity often do not meet the

specified requirements. Of 247 assessed European products, 78% did not comply with EU regulations, and 38 of these products (about 15%) even featured safety-relevant deficiencies.

These results contrast with a high level of conformity amongst products which are put into circulation in the USA based on independent third-party testing. Of the 119 assessed products, 75 % conformed to the requirements and not one single product exhibited a safety-relevant defect.

Therefore, it would be logical that the market surveillance authorities focus their limited resources so that it enhances the focus of their surveillance activities on already highlighted product sectors and in particular on products which have been placed on the market in the course of a pure manufacturer's self-declaration. Products that have been declared compliant by an independent organisation for conformity testing should be given priority because here the authorities may generally assume that the statement of conformity is true.

Independent testing offers protection of a preventive nature and is financed based on the principle of causation.

As a complement to market surveillance by the member states, testing and certification of products by independent third parties in Europe, which is generally voluntary, is a very effective instrument of prevention in order to maintain the necessary protection level.

By testing products before they enter the market, the independent bodies implement the precautionary principle intended by the legislator. Thus, the state respectively the tax payer are discharged from the financial weight especially since the public market surveillance only allows for removal of non-conforming products from the market when damage or harm has already occurred.

This preventive approach is financed by the product manufacturer, importer or trader. The necessity for subsequent state intervention, for which the public authorities have to maintain appropriate resources, is then considerably reduced.

Above all, and for further support of the public sector, the legislator can resort to the system of independent conformity assessment by recognised testing organisations. Moreover, the conformity assessment bodies can be commissioned with technical tasks, such as tests or inspections. This approach can only succeed if the responsibility for protection of citizens and corresponding surveillance measures remains with the public authority and if no conflicts of interest arise or exist between the regular testing activities of the conformity assessment body and the commissioned tasks.[16]

Conformity assessment by independent private organisations therefore provides an efficient deregulation instrument for the legislator.[17]

Overall, preventive testing of products by independent third parties (on a mandatory or on a voluntary basis) and market surveillance by public authorities can be considered complementary instruments to ensure that products in the EU internal market are safe and conforming. Therefore, these instruments should both be strengthened by the European legislator for the protection of citizens.

Independent third-party testing strengthens confidence in mutual recognition

According to the communication, the EC wants to strengthen the principle of mutual recognition, as "national regulations and practices continue to create barriers. National authorities often require specific proof of lawful marketing or simply refuse access to their national market."[18]. Therefore the EC "will also revise the Mutual Recognition Regulation to address administrative fragmentation"[19].

The solution proposed by the Commission, which states that economic operators should in future be granted the possibility "to issue a self-declaration on the product being lawfully marketed in another Member State"[20] is, however, not sustainable because a declaration of conformity by the manufacturer or operator itself does not create the necessary level of trust with a view to potential conflicts of interest.

Rather, the Commission should provide for a conformity assessment by independent third parties as a precondition for a corresponding presumption of conformity with regard to the product marketed in another member state because they are not involved in the design, manufacture, supply, repair or maintenance of the item to be assessed. This means that there is no conflict of interest with regard to assessment results, surveillance or certification. This is the great difference between independent conformity assessment and conformity assessment performed by a manufacturer or supplier.

The confidence in the applicable product-specific regulations and therefore the level of protection secured by the country of origin required for the principle of mutual recognition can be strengthened in the long term by involving an independent third party in the conformity assessment because the third party has proven not only its expertise, but also their neutrality and objectivity to assess the product requirements of the country of origin by means of a statutory accreditation.

Further development within the European standardisation system

As conformity assessment bodies, the members of the VdTÜV use the standards of all standardisation levels to a considerable extent as a basis for conformity assessments. Standards are used by economic operators to describe

a common understanding of what characteristics products or services must meet in order to be safe and conform. Their voluntary application leads to the presumption of conformity with the underlying requirements within the meaning of the respective product-specific European legislative requirements.

Requirement for uniform competence level

As a service provider, conformity assessment bodies themselves must meet differentiated specification standards that describe the state of the art with regard to the organisation and the competence of conformity assessment bodies. The DIN EN ISO/IEC 17000 series of standards helps bring uniformity to conformity assessment and therefore makes a key contribution to the comparability and recognition of conformity assessment results. The same normative basis should be used to ensure a uniform level of competence throughout Europe in the course of the accreditation.

Make extensive use of the ISO/IEC 17000 series of standards

New standardization projects in the area of services can stimulate the European Single Market for services. Here, as the Commission rightly points out, there is still considerable need to catch up when it comes to a common understanding of what requirements the service provider has to meet cross-border.

Services, which correspond to a conformity assessment or are of a similar nature to this, fundamentally require no new normative framework. Here, the VdTÜV recommends the use of the existing series of standards ISO/IEC 17000 to ensure maximum consistency of the normative foundations.

Standardisation – market-oriented, organised and financed by the private sector

The Commission rightly states in its communication that it "needs to be up to these challenges, producing timely and market-driven standards in an inclusive way and consolidating Europe's leadership in international standardisation"[21].

They should therefore standardize where the economic operators identify a corresponding need in the market. This applies in particular for the supporting role of standardisation in innovative sectors such as ICT. The private sector organisation and financing, as well as the national delegation principle, which states that every country is represented in Europe or internationally due to its national standardisation organisation and other players have no voting rights, provide a robust framework for this.

A possible further development of the European standardisation system should necessarily adhere to its constitutive and proven principles for the New Approach.

Create a future-proof single market

Globalization, digitalization, flexibility, demographic change and increasing trade – the economic system and its environment are changing continuously. Against this background, the regulatory framework for the European Single Market – a key factor for European integration, must regularly be put to the test. However, a mere development towards more liberalization will not be sufficient in response to new challenges. Rather, coherent and internationally competitive rules and regulations for the marketing of products and services are required. The New Approach developed and implemented over 30 years ago for product regulation and the Global Approach for the conformity assessment offer the correct systematic concept, which should be taken as a starting point and a framework, within which further development must take place. Sector-specific paths should be avoided in the sense of a coherent regulatory framework for a future-proof European Single Market.

In addition, when revising and redrafting the single market provisions, further care should be taken to ensure that linguistic ambiguities and possible room for manoeuvre in terms of interpretation should be eliminated and avoided as far as possible in the design of statutory provisions in terms of a uniform application practice across Europe. Again, when designing conformity assessment procedures, the corresponding requirements for the obligations of economic

operators should be drafted as clearly as possible, all optimisation potential exhausted and international standards taken into account.

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Increase the level of conformity in the market

In the context of market surveillance, it can be traced over a longer period that the same product groups appear time and time again. On this basis, the Commission should critically review the existing regulatory framework (directives/regulations) on a consistent basis in the wake of the announced compliance initiative'. It is important to question whether the conformity assessment procedures (modules) for the respective product groups can be deemed suitable at all or whether a stricter regime with increased involvement of Notified Bodies in the conformity assessment process is necessary instead for the purposes of a higher level of conformity in the market.

Respond to increased risk potential of new product groups

In addition, the appropriate regulatory framework is also to be determined for the still non-harmonised product groups or entirely new products, depending

on the risk potential resulting from them in particular for the end user. The European legislature must define suitable procedures to ensure the conformity of these products to carry out its responsibilities in terms of protection and care and within the meaning of the principle of precaution.

The VdTÜV provides for the mandatory involvement of the Notified Bodies in the conformity assessment procedure especially in the field of toys, but also for products with lithium-ion battery systems such as E-bikes, Segways, E-scooters, mono-wheels or electric skateboards amongst other things with a view to risks of fire and injury. The same applies to any harmonisation in the area of child care articles (such as buggies, pacifiers).

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Consistent application of the New Approach creates coherence

As the Council already noted in March 2015, an "increasing importance of services to economic output and growth, including through the 'servitization' of manufacturing industries and interconnection between goods and services"[22] has been detected. Of course the regulatory development of the single market for goods and services must take this into account. For the purposes of a coherent overall European legal framework, the regulatory instrument known as the New Approach for product regulation, which has been tried-and-tested for

30 years and is flexible, and the Global Approach for the conformity assessment also must be consistently applied here.

Through innovation or social requirements, products and services in the course of their development must satisfy new expectations. In short: products and services have new requirements and the European legislator has to establish the regulatory framework for this. The most recent example was the proposal of the EC for a directive on the accessibility requirements for products and services on 02/12/2015[23]. The EC has also rightly decided in favour of the application of the New Approach for this new aspect of conformity. For other aspects of the conformity of products arising in the context of new technologies, such as digitization and Internet of things (such as cyber-security for future mobile phone payment systems), the New Approach should also and as much as possible form the basis for the regulatory framework.

Endnotes

1) COM(2015) 550 final "Upgrading the Single Market: more opportunities for people and business", page 18, http://ec.europa.eu/DocsRoom/documents/14007?locale=en
2) A Single Market Strategy for Europe - Analysis and Evidence Accompanying the document, page 96, http://ec.europa.eu/DocsRoom/documents/13405/attachments/1/translations/en/renditions/native
3) http://www.ifia-federation.org/content/wp-content/uploads/Consumer_Product_Safety_Study_2014.pdf
4) A Single Market Strategy for Europe - Analysis and Evidence Accompanying the document, page 97 http://ec.europa.eu/DocsRoom/documents/13405/attachments/1/translations/en/renditions/native
5) COM(2015) 550 final "Upgrading the Single Market: more opportunities for people and business", page 19, http://ec.europa.eu/DocsRoom/documents/14007?locale=en
6) Cf VdTÜV position "Effective market surveillance for Europe"
7) COM(2015) 550 final "Upgrading the Single Market: more opportunities for people and business", page 19, http://ec.europa.eu/DocsRoom/documents/14007?locale=en
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14) Source: UNCTAD statistics - values and shares of merchandise exports and imports, annual, 1948-2010 /. www.statista.de
15) Consumer product safety in Europe: market studies, 2012, 2013, 2014 conducted by IFIA, cf http://www.ifia-federation.org/content/wp-content/uploads/Consumer_Product_Safety_Study_2014.pdf)
16) Blue guide by 2014, page 85, cf http://ec.europa.eu/DocsRoom/documents/12661/attachments/1/translations/en/renditions/native
17) Cf VdTÜV position "Benefits for the State, Economic Operators and Consumers"
18) http://ec.europa.eu/DocsRoom/documents/14007/attachments/1/translations/en/renditions/pdf, page 18
19) http://ec.europa.eu/DocsRoom/documents/14007/attachments/1/translations/en/renditions/pdf, page 19
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21) http://ec.europa.eu/DocsRoom/documents/14007/attachments/1/translations/en/renditions/pdf, page 15
22) http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%206197%202015%20INIT
23) Cf COM(2015) 615 final: https://ec.europa.eu/transparency/regdoc/rep/1/2015/EN/1-2015-615-EN-F1-1.PDF

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