VdTÜV Position: Proposal for reinforcing trust in the Single Market

Worldwide trade is expanding all the time and value added chains increasingly function as global networks. European consumers benefit from a growing number of products, but at the same time they have to be able to trust that the products are compliant and safe. The prerequisite for this is a robust regulatory framework for the EU Single Market.

Placing goods on the market based on harmonised rules or according to the principle of mutual recognition

Products can be placed on the Single Market either based on common EU-wide rules (e.g. toys, machinery, lifts or electrical devices) or through use of the so-called principle of mutual recognition (e.g. furniture or tableware). It is therefore logical and constructive that in the "goods package" presented on 19.12.2017, the EU Commission is seeking to make adjustments in both areas in order to improve the functioning of the Single Market. With regard to market surveillance and also in the area of mutual recognition, the EU Commission has identified "structural weaknesses", which it wishes to counteract by means of two Regulations. However, VdTÜV considers that the measures proposed in these Regulations are not suitable in order to adequately meet today's challenges, eliminate the weaknesses and ensure the most comprehensive compliance possible for the traded products. Therefore, VdTÜV sees a considerable need for correction as regards the legislation proposals, and wishes to comment as follows.

A. VdTÜV-Position on the Regulation laying down rules and procedures for compliance

More than ever, the EU needs a well-organised, coordinated and suitably powerful market surveillance system, in order to identify non-compliant and therefore often also unsafe products as early as possible and instigate suitable countermeasures. Market surveillance should ensure that products fulfil the current requirements for a high level of safety in relation to public interests such as health and safety in general, health and safety at the workplace, consumer and environmental protection and also public safety[1]. However, market surveillance must at its core also guarantee uniform EU-wide enforcement of the Union harmonisation legislation for products, in order to create a level playing field. The purpose of market surveillance is therefore both protection of the health and safety of European citizens at a high level [2], and smooth functioning and fair competition within the single market.

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[1] http://ec.europa.eu/DocsRoom/documents/18027, also the "Blue Guide" compare Page 98

[2] compare 114 Para 3 TFEU: "*The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.*"

Extending the scope of the Regulation

The authority in Brussels correctly states that large amounts of unsafe products are sold in Europe every day. These range from mislabeled products to products posing severe risks to health or the environment. Between 2011 and 2017 alone, there were about 2,500 incidents where illegal products had to be withdrawn from the market. And this is probably only the tip of the iceberg, as the Commission says in its Communication.

However, the current Proposal for a Regulation will not be able to contribute sufficiently to a sustainable and comprehensive reduction in the number of non-compliant products on the market. In comparison with the Draft Regulation "on the market surveillance of products" of 13.02.2013, whose aim was consolidation of all European rules concerning market surveillance, the scope of the present Regulation is clearly curtailed. Only the harmonised products that are listed in the Annex are to be covered. The directive which is decisive for the European consumer is the General Product Safety Directive of 2001 with central market surveillance rules for all consumer products. However, these are not updated by the current Draft Regulation.

In contrast, it does not make any difference to the consumer if products come from harmonised product sectors or from the non-harmonised area. To fulfil the consumer's justified expectations, all products supplied to him must always meet the respective requirements and be safe. Because of its limited scope, the Draft Regulation cannot make a suitable contribution in this respect.

Market surveillance needs stricter statutory provisions

In the Draft Regulation[3], the Commission identifies "insufficient coordination and cooperation between the market surveillance authorities" as one of the greatest problems, along with "insufficient uniformity and rigorousness of market surveillance and border controls". Also, "across-the-board inconsistencies [...] may reduce businesses'willingness to comply with the rules", as the Commission quite rightly says.
In addition, in the Communication "Reinforcing trust in the single market" it can be read that, "Despite a willingness to act at national level, enforcement in the single market for goods is often hampered by a lack of resources (staff, budget, laboratory capacity), coordination and exchange."[4]

Specifying the intensity of sampling

However, the EU Commission does not go so far as to suggest that the frequency and intensity of tests should no longer be left to the discretion of the individual EU member states alone, and instead of this to propose – as expressly demanded by VdTÜV – that a clear, Europe-wide and uniform guide value for the number of samples to be taken by the market surveillance authorities should be defined. The concrete scale of the market surveillance activities and the frequency of

[3] http://eur-lex.europa.eu/resource.html?uri=cellar:0466a6b9-e4b1-11e7-9749-01aa75ed71a1.0001.02/DOC_1&format=PDF, compare Page 61

[4] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017DC0787&from=EN, compare Page 4

tests form the core of the market surveillance measures. The "Blue Guide" rightly states in this connection: "If market surveillance is 'softer' in some parts of the Union than others, weak spots are created which threaten the public interest and create unfair trade conditions."[5]

The concept of "an adequate scale" of samples introduced in the Draft Regulation in Article 15 (1) is far too vague and undefined and, as a result of the resulting opportunity and room for varied interpretation and implementation by the different member states, in the end leads to unacceptable discrepancies and variations in market surveillance practice within the EU. Instead of this, VdTÜV considers the implementation of the current rules by the German Product Safety Act (ProdSG) to be the correct approach. Article 26 ProdSG stipulates a guide value of 0.5 samples per 1,000 inhabitants and year.[6] A stipulation of the scope and size of sampling which defines the required number of samples should therefore be included in the new European legislation.

Defining the concept of adequate resources in relation to authorities

In addition, the national authorities must be provided with sufficient budgetary resources in order to guarantee harmonised market surveillance of the necessary scale and efficacy. The stipulations in Article 12 with regard to the activities of the market surveillance authorities are too vague and undefined, leaving the member states too much room for interpretation. It is not sufficient to expect "effective surveillance of the market" and the taking of "appropriate and proportionate measures", without a definition of minimum requirements.

In the same way, Article 11 (4) should also be made more specific through the addition of harmonised minimum criteria. For although the member states are obliged here to "ensure that their market surveillance authorities and single liaison office have the necessary resources, including sufficient budgetary and other resources, expertise, procedures and other arrangements for the proper performance of their duties", it still remains open what this actually means in practice. In view of such unclear legislation, coherent EU-wide market surveillance practice is unlikely to be achieved in the foreseeable future

Minimum stipulations for sanctions

Article 61 provides for penalties that have to be "effective, proportionate and dissuasive" across the Union. However, the specific form and extent of these penalties is left entirely to the member states. Therefore, harmonisation of the rules is not achieved here to a sufficient extent. When determining the scale of penalties, specific factors should be considered in a uniform way, such as for example the average costs for a conformity assessment which fulfils the requirements, the risk potential of the product with regard to the health of the consumer, third parties and the environment and also the number of nonconformities identified to date on the part of the individual economic operators. The Commission should here at least be empowered to issue specific minimum requirements for penalties within the framework of implementing acts.

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[5] Blue Guide (Version 1.1 – 15-07-2015), http://ec.europa.eu/DocsRoom/documents/12661, compare page 98

[6] ProdSG http://www.gesetze-im-internet.de/englisch_prodsg/index.html

Authorities presume conformity in the case of independently tested products

In view of the well-recognised limited budgetary resources of the member states, however, expansion of market surveillance will probably also only be possible to a very limited extent in future, although at the same time the necessary range of action continues to grow. This clear discrepancy between market surveillance resources and capacity and the volume of goods in the EU single market means there has to be increased concentration and focus on particularly "vulnerable" products.

As long as independent bodies already test products before they are despatched or placed on the market, they are efficiently fulfilling the precautionary principle in the sense of the legislator. This means less expenditure of time and money for the State, as nonconforming products do not have to be identified by the downstream market surveillance authorities financed by the taxpayer and therefore only withdrawn from the market after harm has been caused.

This preventive approach is in fact financed by the manufacturer, importer or by distributors. The necessity for later state intervention to have to provide corresponding resources for the authorities is very considerably reduced.

It would therefore be sensible and logical for the market surveillance authorities to concentrate their limited resources on focussing their surveillance activities on product sectors that have already been identified as problematic, and in particular on products which have been placed on the market based merely on a Supplier's Declaration of Conformity. In contrast, products which have been declared conformant by an independent testing organisation should enjoy a privileged status, as in these cases the authority may basically assume that the statement regarding conformity is true.[7]

Therefore, the risk-based approach as described in Article 12 (2) should be defined more precisely.

Taking growing digitization of products into account

The market surveillance authorities should also be placed under the obligation to take new product risks more strongly into account in the sense of a risk-based approach. This applies in particular to specific risks which are associated with the increasing digitization and/or networking of the products. It is true that according to Article 12 (3), the authorities have to ensure "that a product is withdrawn or recalled from the market [...], if, when it is being used either in accordance with its intended use or under conditions that can be reasonably foreseen, [...] the product [...] is liable to compromise the health or safety of end users". This rule follows on from the still-applicable product safety concept contained in the Product Safety Directive of the year 2001. However, against the backdrop of the challenges posed by digital and networked products, and in particular the growing threats to cyber security, this is no longer sufficient. Instead, it must be demanded here

[7] Overview in graphic form of the reduction in recalls of toys following independing testing in the USA 2008-2017 https://www.cpsc.gov/search?query=cache:sUe0PIrNJZ4J:www.cpsc.gov/safety-education/toy-recall-statistics+recall+toy&site=cpsc_site&output=xml_no_dtd&client=ek_drupal_01&proxystylesheet=ek_drupal_01&ie=UTF-8&access=p&oe=UTF-8

that an ICT product with raised risk potential for people and the environment is also provided with sufficient protective means in order to prevent improper interference by third parties. Products which are not sufficiently robust can considerably endanger the "safety of the end users", and must therefore receive greater attention within the framework of market surveillance. Therefore in such cases also, the possibility must be urgently provided to withdraw these products from the market.[8]

It should be possible to appoint accredited test bodies as Union testing facilities

Article 20 provides for the appointment (notification) of Union testing facilities. It is quite right that these should be sufficiently competent and have sufficient qualified personnel and that they should demonstrate this by means of accreditation. However, No. 3 of the Article goes too far in a manner that is disproportionate when it states that "A notified body or any other conformity assessment body designated pursuant to Union harmonization legislation may not be designated as a Union testing facility". The bodies mentioned here should apparently not be appointed as Union testing facilities, because it is assumed that conflicts of interest with regard to the item to be tested could exist. This provision should be changed to include a stipulation that in the case of notified bodies, for example, such a conflict of interest is simply excluded. In other words, the body shall not have already tested the product to be investigated within the framework of the market surveillance within the framework of its conformity assessment activities in the course of the procedure for placing the product on the market. The body shall also not have supported manufacturers, importers or traders through the provision of advisory services.[9]

Relief of national authorities by independent test bodies

In addition, Article 14, in harmony with the "Blue Guide"[10], should be extended to include the provision that the national market surveillance authorities, in order to relieve themselves of the burden, can call on the system of independent conformity assessment by recognised and accredited test organisations. It should be possible to commission these for technical tasks such as tests or inspections, provided that the responsibility for the protection of citizens and the corresponding surveillance activities remains with the surveillance authority and in so far as no conflicts of interest exist or arise between the test activities of the conformity assessment body and the tasks for which they are commissioned by the market surveillance authorities.

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[8] https://www.vdtuev.de/news/vdtuev-position-regulativer-nachbesserungsbedarf-fuer-sichere-iot-produkte-in-europa?context=436a7e0ac77a42cf9e70e9fa6858bafe

[9] The Blue Guide of the EU Commission in the version of 2016 defines in this sense the necessary independence of independent test bodies when supporting national market surveillance authorities, see Page 104, http://ec.europa.eu/DocsRoom/documents/12661

[10] Blue Guide of the EU Commission in the version of 2016, Page 104, http://ec.europa.eu/DocsRoom/documents/12661 "The market surveillance authority may subcontract technical tasks (such as testing or inspection) to another body, provided that it retains the responsibility for its decisions, and provided there is no conflict of interest between the other body's conformity assessment activities carried out of behalf of economic operators and compliance assessment provided to the market surveillance authority."

B. VdTÜV Position on the Draft Regulation with regard to mutual recognition

Basically, organisations may place their products for which no harmonised rules exist or where only some product aspects are subject to EU harmonised rules on the market, without having to fulfil further requirements (based on the principle established in the ECJ Judgement regarding Cassis de Dijon).

Regulation (EC) No. 764/2008, which is intended to codify and regulate the principle of mutual recognition based on case law, does not have the desired effect. The reason why the principle does not function well is, in the opinion of the Commission, on the one hand the result of too little knowledge of the principle and on the other hand the difficulty - above all of SMEs - of providing evidence that the product complies with the rules of another member state.

Supplier's (self-) declaration does not constitute evidence and does not create trust

A merely formal simplification of the application of the principle for foreign companies will not create trust (which does not currently exist) on the part of national authorities in product conformity which is based on the rules of another member state. In particular, VdTÜV takes a critical view when it comes to the introduction of a supplier's declaration of conformity (Article 4). According to this, in future companies are "to demonstrate to the competent authorities of the Member State of destination that the goods, or goods of that type, are lawfully marketed in another Member State."[i]

VdTÜV considers it completely unacceptable that the authority of the destination country should accept the mere "Declaration" as sufficient evidence when assessing the product, "that the goods are lawfully marketed in another Member State" (Article 4, No. 7 (a)). In addition, it is not permitted to "require any other information or documentation from any economic operator for the purpose of demonstrating that the goods are lawfully marketed in another Member State." (Article 4, No. 7 (b)). Therefore, the hands of the authorities are basically tied.

Principle of mutual recognition is not strengthened

In order that the principle of mutual recognition can be justifiably used by the manufacturer and can also be effective, his products really do have to fulfil the requirements of the country of origin in fact.

However, a simple Declaration, similar to the Supplier's declaration of conformity for products with the CE marking, is not workable. On the one hand, a Declaration is not yet "evidence", and on the other hand a conformity assessment by the manufacturer or seller does not create the necessary level of trust for authorities, consumers and other participants in the market especially with respect to possible conflicts of interest.

The trust in the relevant product-specific national regulations, with the associated guaranteed level of protection which applies in the country of origin and that is necessary in connection with

the principle of mutual recognition, can be sustainably strengthened by involvement of an independent third party in the conformity assessment. For the third party has not only demonstrated its competence by means of a sovereign accreditation, it has also demonstrated neutrality and objectivity in connection with reliable assessment of the fulfilment of the product requirements of the country of origin.

Presumption of conformity for independently tested products

The European legislator should therefore step back from a "Declaration of mutual recognition". Rather, the application of the principle of mutual recognition should be encouraged in that manufacturers who have the conformity of their products tested voluntarily by accredited and independent bodies are accorded the benefit by the authorities that the voluntary testing initiates a special presumption of conformity. This would create an incentive to adhere to the legally applicable rules and regulations.

The Draft Regulation must be correspondingly changed, so that the principle of mutual recognition can function more effectively in actual practice.

Only testing by accredited independent third parties can initiate a corresponding presumption of conformity with regard to the product which is originally placed on the market in another member state, and therefore regenerate the trust of the authorities of the destination country in the thereby guaranteed level of protection in the country of origin. The Declaration at the most reveals which rules and regulations the manufacturer wished to follow.

[i] http://eur-lex.europa.eu/resource.html?uri=cellar:d47e2d52-e4b2-11e7-9749-01aa75ed71a1.0003.02/DOC_1&format=PDF