TÜV VERBAND

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Toy safety in the EU – not a success story

TÜV Association | Position on the evaluation report of the Toy Safety Directive

Introduction

The Toy Safety Directive[1] of 18 June 2009 is a central part of EU sectoral product legislation. It lays down the safety and other requirements that toys must meet before they can be placed on the EU market. It has two main objectives: (1) to ensure a high level of safety of toys with a view to ensuring the health and safety of children and, (2) to guarantee the functioning of the internal market for toys. As a so called 'New approach' directive, it defines all the necessary elements for an effective conformity assessment, accreditation and market surveillance.

On 19 November 2020, the European Commission published its evaluation report[2] of the Toy Safety Directive providing, amongst others, conclusions on its effectiveness and efficiency. The report states that the directive has been effective in setting up harmonized EU-wide safety requirements for toys. When it comes to their effective enforcement, however, the Commission finds that there is still room for improvement. No recommendation is given on whether the directive should undergo a revision.

The TÜV Association welcomes the Commission's efforts to undertake this product sector a detailed evaluation, and would like to comment on some key statements and findings of the report. Generally speaking, the high number of non-compliant toys gives clear evidence that the directive has failed to protect children adequately. While the stipulated safety requirements can be considered as comprehensive, the compliance rate of toys with these requirements is clearly insufficient. This clearly demonstrates that the prescribed conformity assessment procedure merely relying on a self-declaration by the manufacturers is not sufficiently effective. Too many manufacturers do not fulfil their responsibilities to ensure the health and well-being of children as the most vulnerable consumers.

The TÜV Association calls on the European legislators to undertake the Toy Safety Directive an in-depth revision by prescribing mandatory third-party conformity assessments for toys. Evidence from the United States clearly suggests that an ex-ante assessment by independent bodies leads to a significant lower number of non-compliant toys. Furthermore, the revision should also address IT security to become an integral part of the product safety requirements. The risk potential of connected toys must be re-assessed. Toys must be both safe and secure. To demonstrate compliance with the requirements, the Cybersecurity Act[3] should be applied.

[1] see 2009/48/EC
[2] see SWD(2020) 287 final
[3] see (EU) 2019/881

The status quo: High non-compliance rates and weak enforcement

A large number of toys are non-compliant with the requirements

The core objective of the Toy Safety Directive is to ensure a high level of safety of toys with a view to ensuring the health and safety of children. The sole indicator to measure the level of safety is the number of non-compliant toys that are circulating in the EU Single Market.

The EU wide Rapid Information Exchange System called 'Safety Gate' (formerly RAPEX) provides an overview on the number and types of unsafe products detected by market surveillance authorities. Out of all products listed in the system, toys have year by year been topping the list as the product category with the highest non-compliance rate. In the 2020 statistics, 27% of all notifications were related to unsafe toys, far ahead of motor vehicles (21%) and electrical appliances (10%). Moreover, the number of toy notifications has even more than doubled between 2011 and 2018 (p. 28) as shown in the evaluation report. In addition, nearly 50% of all toy notifications in 2018 were related to chemical risks (p. 29).

These alarming figures are supported by findings of Joint Market Surveillance Actions quoted in the evaluation report:

„By comparison, four joint market surveillance actions on toys, supported by the Consumer Programme of the European Commission, showed non-compliance rates for the tested toys between 10% and 96%, with an average of 43%." (p. 50f)

Although the Commission – without any compelling arguments – dismisses the relevance of these figures (cf. p. 29), it is obvious that they provide clear evidence of a high non-compliance rate. Whereas an incorrectly labelled toy may not have direct safety implications, breaches of chemical, electrical or physical requirements do harbour significant safety risks for children, however. Children are, after all, the most vulnerable consumers being significantly affected by intrinsic material defects or harmful chemicals.

The European legislator has thus a particular duty of care, which is not sufficiently incorporated in the current Toy Safety Directive. The fact that the EU legislator is called upon to act here not least arises from Article 169 of the Treaty on the Functioning of the European Union (TFEU), which obliges the EU to ensure a high level of protection for consumers. Similarly, Article 38 of the EU Charter of Fundamental Rights calls for a high level of consumer protection. The objective of consumer protection and thus product safety has long been recognised in the case law of the European Court of Justice (ECJ) as part of the important general interests. Safety is expressis verbis part of consumer protection, whereby this is generally understood to mean product safety.

Market surveillance has proven incapable to detect the high number of non-compliant toys

As regards control mechanisms, the Toy Safety Directive almost entirely relies on the instrument of ex-post market surveillance. National market surveillance authorities face the challenging task of detecting unsafe toys by inspecting random samples, targeting economic operators and withdrawing non-compliant products from the market.

However, over the last years, the system of market surveillance has not been able to manage the continuously growing amount of defective toys. In its evaluation report, the Commission admits that:

"With the 'Sales of traditional games and toys' projected to between € 18 billion and € 20 billion per year between 2014 and 2016, it can easily be assumed that the number of toys placed on the EU market every year may be counted in billions. Compared to the figures in the 2014 – 2018 reports above, market surveillance could appear to be ineffective." (p. 50)

There is no doubt that this conclusion is valid, albeit it does not come as a surprise. Market surveillance authorities lack the resources and capacity to detect an adequate number of non-compliant toys in relation to the enormous number of toys placed on the market. Moreover, their operational power differs significantly between member states. Contrary to the expectation raised in the evaluation report, however, the recently introduced Market Surveillance Regulation[4] will not be able to lead to a sufficient improvement in terms of enforcement. The closer coordination and cooperation between the different market surveillance agencies foreseen is not sufficient by itself. Agencies would need to be equipped with tremendous additional human and operational resources. This, however, appears to be completely unrealistic.

Generally speaking, an ex-post market surveillance will only be able to detect the tip of the iceberg. This is because of the sheer amount of toys, but also because apparent non-compliances such as mechanical failures will be easier to detect by consumers and market surveillance authorities than more 'concealed' risks requiring laboratory testing such as chemical risks. Thus, rather than viewing market surveillance as the only enforcement tool for product safety, it should be considered as a reporting system indicating the safety level in the EU Single Market. By its nature, it can only focus on products that have already been produced and are circulating, but cannot systematically prevent unsafe products from entering the Single Market. This, however, should be the objective of an effective control instrument. Put differently, what is needed are more robust ex-ante compliance mechanisms.

[4] see also (EU) 2019/1020

The risk potential of toys is not adequately reflected in the conformity assessment options

The European product legislation framework is built on a risk-based approach. For products with a low risk, the manufacturer has the option to self-declare that his product complies with all relevant safety provisions stipulated in the respective EU product legislation. Only for products with a higher risk potential must the manufacturer involve an independent assessment organization (so-called Notified Body) mandatorily.

The Toy Safety Directive gives the manufacturer the choice between two conformity assessment options: A self-declaration by the manufacturer (module A) or an independent certification by a Notified Body (module C). The evaluation report states that "Evidence from Notified Bodies suggests that around 97% of toys in the EU market are subject to the self-verification procedure" (p. 13).

Based on these facts, two conclusions should be drawn: Firstly, by granting the manufacturer the self-assessment option, the European legislator essentially indicates that toys only harbour a low risk potential. This stands contrary to the previous observation that the European legislator has a particular duty of care vis-à-vis children in view of the multiple risks associated with toys. This is all the more important when considering that modern toys do not only harbour risks associated to their functional safety, but that their increasing connectivity yields new risks for their IT security such as hacks by unauthorized external parties. The current directive is outdated in that it only comprises safety requirements, but does not incorporate security aspects. Reports from consumer organisations[5] have shown how easily connected toys can be hacked.

Secondly, these figures show that the high non-compliance rates of toys can be directly attributed to the fact that the self-assessment option is not an adequate and reliable means to generate the necessary level of compliance in the market. What is needed are effective ex-ante control mechanisms that ensure that only safe toys are produced and placed on the EU market.

In conclusion, the arguments made above clearly demonstrate that the current Toy Safety Directive has not achieved its intended outcome in that it has failed to ensure a high level of safety. The TÜV Association therefore strongly advocates for a review of the directive by focusing on two main aspects: Strengthening compliance through independent conformity assessment bodies and incorporating IT security requirements by making use of the Cybersecurity Act.

[5] see https://www.beuc.eu/publications/beuc-x-2016-136_mgo_letter_to_giovanni_buttarelli_-_edps_-_connected_toys.pdf

Strengthening compliance through independent conformity assessments

Prescribing a mandatory ex-ante assessment by Notified Bodies

The alarming numbers on non-compliance rates and the ineffective market surveillance should be a wakeup call that the status quo cannot be regarded as acceptable anymore. There is an urgent need for action. When it comes to available policy options to remedy this situation, the TÜV Association advocates implementing the precautionary principle for toys ambitiously. The introduction of mandatory ex-ante conformity assessment by independent bodies (so-called Notified Bodies) must be considered as the only risk-adequate option.

Within the EU, the involvement of Notified Bodies is to date mandatorily prescribed for high-risk products such as machines, lifts or medical devices. In light of their risk potential, toys must be subject to equal conformity assessment procedures.

Third-party involvement has several advantages. Most importantly, as these assessments are already carried out during the development phase or production process, unsafe toys can be identified at a very early stage and manufacturers are forced to react immediately. If they do not do so, they do not receive a certificate. Third-party participation also benefits the environment, as it prevents the shipment, often even the production, of non-compliant products increasingly originating from overseas. Moreover, an ex-ante assessment generates trust in the safety of toys. Finally, third-party certification also reduces the burden on market surveillance authorities. It is based on the cost-by-cause-principle in that the external assessment is financed by the manufacturer himself, in contrast to market surveillance activities borne by taxpayers.

The competence and impartiality of the conformity assessment body is ensured through a process of recognition and accreditation carried out by public authorities and continuously monitored by the member states. This guarantees that the independent conformity assessment bodies throughout Europe have the necessary competence. Official accreditation is the guarantee of reliability, credibility and trust.

An independent conformity assessment body such a TÜV organisation is 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.

The value of third-party conformity assessment: Evidence from the United States

The benefit of third-party conformity assessment can be illustrated by comparing the U.S. with the EU regulatory model. As a direct consequence of the Mattel scandal, where over 19 million toys with lead paints produced in China had to be recalled in 2007[6], the United States introduced the US Consumer Product Safety Improvement Act in 2008. It prescribes a mandatory third-party

[6] see https://www.nytimes.com/2007/08/15/business/worldbusiness/15imports.html

conformity assessment for all toys.

A scientific study[7] published in the International Review of Administrative Sciences in 2018 compared the effectiveness of the two regulatory models (self-assessment vs. third-party assessment – 3PA). It finds that the number of toy-related recalls were ten times higher in the EU than the number of recalls in the US. With similar toy safety standards, the two authors conclude by arguing:

"Analysis of the 3PA model suggests gains in safety benefits that extend across all toy-related product categories, with a consistently lower number of recalls not only at the aggregate level, but in virtually every hazard area. Analysis of the EU model (Supplier's Declaration of Conformity; SDOC) of conformity assessment shows higher total numbers of recalls of violative products that reached the market. (…) For both regions this finding lends support to our hypothesis that the additional third-party scrutiny given to products seeking certification under 3PA provides significant protection to consumers over the SDOC model. In starker terms, because the conformity assessment system prevents products with recognized safety problems from entering the market (…)." (p. 11).

Even though the Commission evaluation report refers to this study, the results are dismissed with the argument that the study does not take into account the intensity of market surveillance in the EU (cf. p. 13). However, given the fact that the same report admits that "the effectiveness of market surveillance can be considered as limited" (p. 51), this argument does not hold.

The value of third-party conformity assessment: Evidence from Germany

Although third-party conformity assessment for toys is not mandatorily prescribed in the EU, it is partly stipulated on a voluntary basis in national legislation. A good example is the German GS mark.

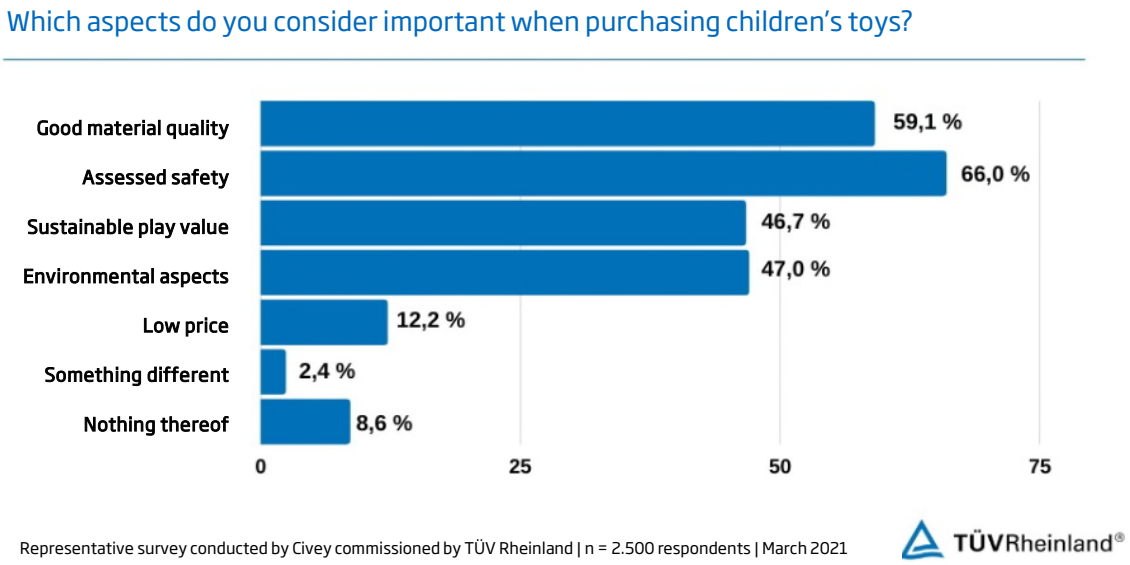
The GS mark ("Assessed Safety") is a voluntary certification mark that manufacturers can obtain for their products. To do so, the product must comply with the requirements laid out in the German Product Safety Act (Produktsicherheitsgesetz) which foresees the involvement of an independent certification body. This independent assessment is not limited to a type examination of the product, but also comprises the continued monitoring of the overall production process.

The GS certification mark is well known among German consumers and often found on products in German stores. A representative survey[8] from March 2021 commissioned by our member TÜV Rheinland asked German consumers which criteria they consider to be important when

[7] see Larson, D./Jordan, S. (2018): Playing it safe: toy safety and conformity assessment in Europe and the United States. *International Review of Administrative Sciences* 85(4), 763-779.
[8] see https://presse.tuv.com/spielzeug-orientierungshilfe-fuer-nachhaltigen-spielwert/

purchasing toys. Assessed safety ranked on top with 66% of respondents, followed by good material quality (59%) and environmental aspects (47%). Remarkably, a low price was named by only 12% of respondents.

These findings illustrate that for consumers, safety and quality considerations trump price sensitivity.



Countering misleading assumptions about third-party conformity assessment

Unfortunately, the evaluation report falls short of taking into account the arguments on the value of third-party assessment. Rather, the report makes several critical assumptions about its role and functioning. This is surprising given that for other high-risk product categories, the European Commission prescribes the mandatory involvement of third-party bodies. This paper engages with two prevailing assumptions made in the report.

<u>Conformity assessment and costs</u>

"Getting a third party approval thus appears to add a further delay to the marketing of a toy, and additional costs." (p. 73)

The cost argument is probably the most prevailing in that third-party conformity assessment is merely perceived in terms of being an additional financial burden for the manufacturer. The TÜV Association does not share this view. As a matter of principle, safety considerations should never be compromised by financial considerations. This is in particular true for children as the most vulnerable consumers.

Considering the costs, it must be emphasized that the assessment of a product is usually time-consuming and associated with costs – if done with care - regardless of whether an external body

is involved or not. Manufacturers must assess their product with regard to its conformity in any case requiring human expertise as well as testing equipment. The only difference in financial terms is the certification part itself, which, however, represents only a small part of the overall costs. Rather than seen as a burden, getting a third-party certification should be considered as a quality feature – a unique selling point. In addition, the introduction of mandatory third-party conformity assessment would lead to a better level-playing field given that rogue operators are more restrained from selling their products on the European market.

The availability and control of conformity assessment bodies

„In addition, if all toys were to be subject to an EC-type conformity assessment, this would require a considerable increase in the number of notified bodies, since only around 3% of the toys in the EU market have so far been subject to third-party testing. Linked to this would be considerable more efforts, and costs, to control laboratories' quality." (p. 73)

While it may be true that more Notified Bodies are required, the underlying assumption that many conformity assessment bodies do not have the capacity is not shared for two reasons. On the one hand, a large number of conformity assessment bodies already has the human and operational resources to engage in this field. A good example is the previously mentioned German GS mark in which both national and foreign conformity assessment bodies are involved. On the other hand, capacities can be built up quickly if there is a growing demand. The Covid-crisis has shown that conformity assessment bodies were very capable to meet market needs and to build up laboratory capacity within a few weeks when needed.

When it comes to the control of laboratories, an extensive network of accredited conformity assessment bodies is already in place, also due to the fact that many laboratories owned by the manufacturer are accredited themselves. Hence, the control capacities (accreditation) are to a large extent already in place. Apart from that, the costs of accreditation are entirely borne by the conformity assessment body itself. Rather than presenting an effort, third-party certification helps to reduce the burden on the authorities and market surveillance as previously demonstrated.

Establishing the digital security of smart toys

Expanding the product safety definition to include digital security

The current Toy Safety Directive does not correspond to the technological progress anymore. The general safety requirements (Article 10 (2)) and the particular safety requirements (Annex II) of the directive only focus on the functional safety of toys such as mechanical, electrical and chemical safety. Cybersecurity protection was not on the agenda at the time of the last review. Therefore, cybersecurity protection objectives and requirements such as an adequate protection against external attacks and measures to protect the right to privacy are completely missing in

the current directive dating back to 2008.

This regulatory gap is nonetheless crucial and has to be closed given that more and more toys are becoming connected. While a smart watch might be safe to use, it can still pose a privacy threat. These kind of watches often have an unencrypted communication channel with their backend server. In this case, the watch is not enough cyber secure allowing hackers to penetrate into the software and, for example, locate the child through the GPS function. Consumer protection organisations have repeatedly detected severe privacy and security issues of connected toys and with good reason called for corresponding regulatory action[9].

Therefore, the definition of a safe toy must be extended to include digital security ensuring a risk-adequate robustness. A toy must be both safe and secure. Digital security has already been regulated in the Medical Device Regulation, and is included in the recent proposal for a new Machinery Regulation. The consideration made in the evaluation report that cybersecurity requirements will be covered by the delegated acts of the Radio Equipment Directive is insufficient. Cybersecurity provisions should be an integrated part of a complete set of essential health and safety requirements laid down in the Toy Safety Directive. Moreover, the reference to the Radio Equipment Directive is not convincing as the RED does not foresee a mandatory third-party assessment which, however, would be appropriate due to high risk potential of toys.

Reassessing the risk potential of smart toys

In addition to defining the requirements with regard to IT security, it is important to consider that the risk potential of smart toys often changes due to their connectivity. The example with the smart watch mentioned above demonstrates that a new security risk may arise which is not covered by the risk analyses currently prescribed in the Toy Safety Directive. For this reason, the risk potential of smart toys with view to connectivity must be re-evaluated. It must be ensured that the manufacturer's risk analysis relating to all the relevant cybersecurity aspects of the smart toy is of an appropriate and reliable quality. If connectivity significantly enhances the risk posed by a toy, the involvement of a Notified Body must be mandatory if there is a risk to life, limb, privacy or other substantial legal interests of the child.

Making use of the cybersecurity schemes as part of the Cybersecurity Act

With the Cybersecurity Act (CSA)[10], the European legislator has established an EU-wide certification framework addressing the cybersecurity of products, processes and services. Through different certification schemes, the manufacturer can prove that his product encompasses a certain level of cybersecurity protection. In line with a risk-based approach, each

[9] see https://www.beuc.eu/publications/beuc-x-2016-136_mgo_letter_to_giovanni_buttarelli_-_edps_-_connected_toys.pdf
[10] see (EU) 2019/991

scheme differentiates between the three assurance levels 'basic', 'substantial' and 'high'. Whereas a self-declaration by the manufacturer is an option for the basic assurance level, a certification by independent third-parties is required for the assurance levels substantial and high on the basis of the CSA.

ENISA, the responsible authority for the CSA, is already envisaging a new scheme for Consumer IoT products. This scheme should be used to demonstrate compliance with the essential cybersecurity requirements laid down in a revised directive/regulation. This close link is already established in the recent proposals for a new AI Regulation and for a new Machinery Regulation and should be equally included here.

In a nutshell, the CSA should be an integral part of the future toy safety legislation with regard to cybersecurity and its assessment.

Recommendations for action

In conclusion, the Toy Safety Directive urgently needs to undergo a revision taking into account the following two central aspects:

1. Prescribing mandatory third-party assessments for toys

Toys harbour significant safety risks for children that can affect their life, limb and privacy. The high non-compliance rates of toys circulating in the European Single Market are alarming and demonstrate that a mere self-declaration of conformity by the manufacturer is not sufficient. The European legislator should remedy this situation by strengthening the precautionary principle. Toys that pose potential risks to life, limb, privacy or other substantial legal interests of the child, as well as toys which are used by children up to three years of age, must be subject to a mandatory ex-ante assessment by independent conformity assessment bodies.

2. Establishing the digital security of toys

Toys must not only be safe but also secure, meaning they must be adequately robust to avert external attacks and misuse. This cybersecurity aspect is to date completely missing in the current directive. The European legislator is called upon to stipulate such requirements in the essential health and safety requirements. The Cybersecurity Act should be utilized to demonstrate compliance with these requirements. Moreover, the risk potential of connected toys should undergo a re-evaluation to account for these new risks.

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