

Developments

Severe Regulations for Toys in the European Union: The New EC Directive from a German Perspective

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A. Introduction

On 18 December 2008, the European Parliament accepted the proposals of the European Commission¹ for amendment of the toy directive.² The modifications are published in the Official Journal of the European Communities.³ Following publication of the new directive, the member states have 18 months in which to transpose it into national law. In Germany, in all probability, this will occur in the 2nd Ordinance to the German *Geräte- und Produktsicherheitsgesetz* (GPSG - Equipment and Product Safety Act). The revised laws will apply two years after the directive has come into force, while the new threshold values for heavy metals will apply in four years. Until then, the old rules will continue to apply. Thus the directive, which is over 20 years old, has been revised following increasing reports of unsafe toys, particularly, though not exclusively, from China. The aim of the amendment is to ensure that toys do not pose any health risks or risks of injury, thus achieving a reduction in the number of toy-related accidents.⁴

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¹ *Proposal for a Directive of the European Parliament and of the Council on the Safety of Toys*, COM (2008) 9 final (Jan. 25, 2008).

² Council Directive 88/378, 1988 O.J. (L 187) 1 (EC).

³ Council Directive 2009/48, 2009 O.J. (L 170) 1 (EC).

⁴ See Press Statement by the European Commission, IP/08/2026 (Dec. 18 2008), available at <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/2026&format=HTML&aged=0&language=EN&guiLanguage=en>; recital 11 of the directive.

B. New Approach in the European Union (EU)

The toy directive is part of the new approach of the EU. The aim of the concept⁵ introduced in 1985 was a new approach to technical harmonisation and standards from machinery to voltage standards as well as to toys and thus the promotion of trade within the EU. The objective was to allow manufacturers as much autonomy as possible in the manufacture of their products. Government control was to apply mainly to the monitoring of products already on the market. Apart from that, monitoring was only considered for products with a particularly high risk potential. At the same time, however, the objectives of guaranteeing citizens' safety and health and protecting the consumer were also pursued.

The new concept comprises the following basic principles:

- Harmonisation is restricted to the essential safety requirements and does not go into detail.⁶ Indeed, on account of technical progress and the great number of technical rules, full harmonisation would hardly be possible. This system is considerably more flexible than continual revision of the directive. By means of the essential safety requirements, the directives define the desired result with regard to product safety. They do not stipulate the path that has to be taken to achieve that result.
- Only such products that satisfy the essential safety requirements may be put into circulation or may be applicable for manufacturing purposes.
- The technical details are not elaborated by the institutions of the EU in the directives, but by the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) and the European Telecommunications Standards Institute (ETSI). This principle of the division of work was introduced for the first time as part of the new approach.⁷
- There is a rebuttable presumption that products manufactured in compliance with the harmonised standards satisfy the essential safety requirements.⁸
- The application of the harmonised standards remains voluntary for the manufacturer. In a legal sense, the requirements of the directive concerned are decisive. The product manufacturers are only obliged to satisfy the essential

⁵ See Council Decision, 1985 O.J. (C 136) 1.

⁶ See Arun Kapoor & Thomas Klindt, "New Legislative Framework" im EU-Produktsicherheitsrecht - Neue Marktüberwachung in Europa?, 19 EUROPÄISCHE ZEITSCHRIFT FÜR WIRTSCHAFTSRECHT (EUZW) 649, 650 (2008).

⁷ See Stephan Krieger, *Das technische Umweltrecht der Gemeinschaft nach der "Neuen Konzeption,"* 12 UMWELT-UND PLANUNGSRECHT (UPR) 401 (1992).

⁸ See Thomas Klindt, *Verbraucherschutz durch Integration sicherheitsrechtlicher Anforderungen in die Gerätekonstruktion,* 16 VERBRAUCHER UND RECHT (VUR) 394, 396 (2001).

safety requirements laid down in the directives.⁹ This opens up the possibility for the manufacturers to manufacture their product in a way that departs from the harmonised standards, using innovative technologies. Having said that, the presumption of conformity as regards compliance with the harmonised standards does not apply here.

The new approach is complemented by the Global Concept of Certification and Testing.¹⁰ This involves the mutual recognition of product tests. Basically, the Global Concept governs the conformity assessment procedure and certification. Labelling the products with the CE marking depends on a product extermination carried out in accordance with these standards.

Meanwhile, since 1987, more than 20 directives have been issued on the implementation of these concepts. Among these directives, for example, are the better known directives on machinery¹¹ and medical devices.¹² We must differentiate here between risk-specific (so-called "horizontal") directives and product-specific (so-called "vertical") directives. Horizontal directives cover various groups of products which pose a single specific risk. For example, this group includes the low voltage directive.¹³ Vertical directives refer only to a single product group, but it is one which poses various different risks. Like the recreational craft directive¹⁴ and the lifts directive,¹⁵ the toy directive is a member¹⁶ of this group.

In the meantime the new approach has been revised by the decision of the European Parliament and the Council of the European Union¹⁷—commonly known as the “new legislative framework.” The new concept provides the general framework and model conditions for the revision and the creation of new directives. Furthermore the regulations for market surveillance were tightened and new regulations for the accreditation of the

⁹ See Kurt-Christian Scheel, *Auslegung von EU-Richtlinien und Entscheidungsbefugnis der Kommission*, 45 GEWERBEARCHIV (GEWARCH) 129, 130 (1999).

¹⁰ See COM (1989) 209 final (July 24, 1989).

¹¹ See, e.g., Council Directive 06/42, 2006 O.J. (L 157) 24 (EC).

¹² See, e.g., Council Directive 07/47, 2007 O.J. (L 247) 21 (EC).

¹³ Council Directive 06/95, 2006 O.J. (L 374) 10 (EC).

¹⁴ Council Directive 94/25, 1994, O.J. (L 164) 15 (EC).

¹⁵ Council Directive 95/16, 1995 O.J. (L 213) 1 (EC).

¹⁶ See Kapoor, *supra* note 5.

¹⁷ See Council Decision 768/08 of 9 July 2006, 2008 O.J. (L 218) 82.

conformity assessment bodies were created.¹⁸ The new toy directive is not yet based on the new legislative framework. This concept shall only be applicable for future directives.

C. Experience with the Previous Toy Directive

The background to this revision of the directive was the increasing number of product recalls related to unsafe toys. The recall of more than 20 million toys by the manufacturer Fisher-Price / Mattel in 2007 made headline news.¹⁹ The toys concerned contained large quantities of the heavy metal lead, which can cause poisoning with prolonged body contact. Lead inhibits enzymes in the body, disrupting the oxygen supply. The consequences are chronic tiredness, headaches and drastic weight loss. The toys were made in China.

According to the previous toy directive, toys were allowed to contain hazardous substances such as lead or carcinogens provided that these substances did not surpass a certain threshold value. There were calls for this to be changed. There were also demands for the obligations on importers to be extended in view of the fact that, as regards the often elusive non-European manufacturer, manufacturers' liability was in most cases just as ineffective as the powers of the authorities in their enforcement of product safety laws.

A case in the USA, in which a child actually died, also caused a stir. The child swallowed several very powerful magnets which had detached themselves from the toy. The magnets collected inside the child's body and caused it to suffocate.

These examples show that the old regulations were not severe enough. In order to ensure consumers health and security the European Union took the decision to tighten up existing laws.

D. New Requirements for Toys

An essential safety requirement for toys—as in the old version—is that when being used as intended or in a foreseeable way they do not pose any dangers to the user or to third parties. The following detailed revisions—the list that follows is merely a selection—have been enacted:

¹⁸ See Council Regulation 765/08 of 9 July 2006, 2008 O.J. (L 218) 30 (EC).

¹⁹ See the Press Release from Mattel, available at <http://www.mattel.de/service.php?action=topfaq&qid=1186040950&f>.

I. Chemical Requirements

In the new version, toys must not contain any carcinogenic, mutagenic or reprotoxic substances (so-called CMR substances). That said, the threshold values of all other general chemicals law of the EU also apply to toys: they state that such substances are allowed to be present in concentrations of up to 0.1 percent. Exceptions to this apply only to toys designed for children under the age of 36 months and only for nitrosamines and nitrosable materials.

In order to reduce the risk of allergies, a list of 55 allergenic substances has also been incorporated²⁰ in the directive, with toys only being allowed to contain traces of the mentioned substances up to a threshold value of 0.01 percent.

Furthermore, revised laws and threshold values applying to the use of heavy metals have been introduced.²¹ This shows that the call for the total prohibition of heavy metals in toys, which was made in connection with the recall of the Mattel toys, was not successful in achieving the desired change in regulations. However, the threshold values have at least been lowered. They do not apply to toys in the use of which all kinds of danger can clearly be excluded if they are sucked, licked, swallowed or come into contact with the skin for prolonged periods.

In a nutshell toys can even after having tightened up the toy directive include dangerous substances.

II. Mechanical Requirements

The mechanical requirements for toys have also been tightened. For example, it has now been made clear that toys must be constructed in such a way that danger of suffocation or strangulation can be excluded.²² One of the main demands that were made after the death of a child by suffocation as a result of having swallowed magnets from a toy has thus been implemented. Another revision is that toys contained in food products must be packaged separately. Toys to which access can only be gained by actually consuming the food attached to them are now completely prohibited. If however the food itself serves merely as a package, this remains permissible, contrary to the status in the USA, for example. Thus the *Überraschungsei* (surprise egg), very popular in Germany, continues to be allowed under the new directive. As regards sound emissions, toys may only emit such sounds (impulse or constant) as do not cause damage to the child's hearing.

²⁰ See Council Directive 09/48, 2009 O.J. (L 170) 1 (EC) (Annex II, III, 11).

²¹ See *id.* at Annex II, III.

²² See *id.* at Annex II, I.

III. Electrical Requirements

A new feature concerning the electrical requirements for toys is that even in the case of foreseeable malfunctions the toys must afford protection against electrical dangers and continue to be safe to use. In addition to that, injuries connected with laser, LED and any other kind of radiation must be able to be excluded.

IV. Hygiene

It must be possible to clean toys for children under 36 months. Under the revised law, textile toys must be washable.²³

V. CE Marking

The requirements concerning the CE marking, which were already called for in the previous amendment, have now also been tightened. For example, in the case of packaged toys, the CE marking must also be applied to the package if it is not otherwise visible from the outside.²⁴

In view of the fact that unsafe toys have found their way on to the market again and again in spite of the requirement for the CE marking, the directive's new amendment has put in place more stringent national market surveillance systems. Member States now have powers, for example, to prohibit dangerous toys or to remove them from the market. They can also order the destruction of particularly dangerous toys. However, note should be taken of the fact that on the basis of § 8 of the GPSG the authorities in Germany actually already held comparable powers. According to § 8 para. 4 of the GPSG, the supervisory authorities can order appropriate measures to be taken, such as prohibiting the launch of a product, or ordering a recall or even the destruction of the products concerned if they suspect that they do not comply with the requirements of the GPSG and are therefore to be classified as unsafe.²⁵ The aim of these drastic measures was to ensure that the requirements for the CE marking, which are checked by the manufacturers themselves and not by independent laboratories, are also met.

²³ See *id.* at Annex II, V.

²⁴ See *id.* at art. 17.

²⁵ See Thomas Klindt, § 8, in *GPSG Kommentar* (Thomas Klindt ed., 1st ed. 2007), margin numbers 49-116; Thomas Wilrich, § 8, in *GPSG* (Thomas Wilrich ed., 1st ed. 2004), margin numbers 22-66; Joachim Geiß & Wolfgang Doll, § 8, in *GPSG Kommentar* (Joachim Geiß & Wolfgang Doll eds., 1st ed. 2005), margin numbers 50-71.

However it is feared that also unsafe toys will come on to the market until there are no independent checks before products' release.

VI. Warnings

The provision covering warnings²⁶ has also been tightened. Toys for children under 36 months, for example, now have to be specially labelled. Note should be taken of the fact that a toy must not be labelled with a warning if the latter contradicts the use of the toy as intended in terms of its functions, dimensions and properties. A notice stating that a toy is not suitable for children under 36 months is therefore not allowed if it is clear that the toy was intended for just that age group. If a toy or toys are contained in food products, a warning with the words "Toy inside; adult supervision recommended"²⁷ must be issued on the package.

Warnings, when used without additional measures, could be problematic, because many users do not read warning labels. It is better to manufacture the products that are safe than to label the products with a warning. So these regulations will not fulfill the expectations.

E. Manufacturers' Obligations

The new directive places manufacturers under obligation to maintain comprehensive technical documentation covering all their toys.²⁸ They must, for example, keep a file of their products listing all the measures they have taken to ensure that the mentioned products comply with the safety requirements. Apart from that, they must carry out one of the conformity assessment procedures described in more detail in the relevant *Deutsches Institut für Normung* (DIN - German Institute for Standardization) standard or have such a procedure carried out. Manufacturers are also required to make sure that operating instructions which can be understood easily and comprehensive warnings are enclosed with or affixed to the toys. The warnings must be in a language understandable to the consumer which needs to be defined by the respective Member State

²⁶ See Council Directive 09/48, art. 11, 2009 O.J. (L 170) 1 (EC).

²⁷ See *id.* at Annex V, B, 1.

²⁸ See *id.* at art. 4.

F. Obligations of Retailers and Importers

In future, retailers and importers will be required to check whether or not the manufacturer has carried out the conformity assessment procedure properly and whether or not the conformity label has been affixed.²⁹ They will also have obligations relating to market surveillance. The details of the legal consequences of a breach of these obligations remain unclear. The directive instructs the Member States to fix appropriate sanctions, which may also be penal in the case of severe contraventions. The sanctions are to be reasonable but also to act as a deterrent, and may be more severe in cases where the directive has been contravened on more than one occasion. It is to be expected that the German legislators will adopt the previous sanctions of the GPSG or fix similar ones. In the legal situation as it has been to date, those contravening the directive face fines of up to 30,000 euros³⁰ and imprisonment of up to one year³¹ if the contravention is repeated persistently and if said contravention jeopardises the life or health of another person or third-party possessions of significant value.

G. Summary

Viewed in its entirety, the revised directive has tightened up the existing laws in several respects. Be that as it may, the new toy directive has been the subject of much criticism to the effect that it does not actually go far enough.³² There have, for example, been complaints that the threshold values for chemicals are still too high, and that the fact that children often put toys in their mouth has not been sufficiently taken into account, or with modelling clay, for example, that there is very close skin contact. There are demands to the effect that regulations should be applied to toys which are as stringent as those applied to food or cosmetics. In addition, there is the generous period of grace applying to chemicals, which do not have to meet the new threshold values until four years have expired. There has also been criticism of the fact that the call for an inspection of toys by independent test laboratories and not by the manufacturer himself has not become part of the directive, although the German government made efforts in support of such a move.³³ To be on the safe side, consumers in Germany should look for the GS mark (*Geprüfte*

²⁹ See *id.* at arts. 6, 7.

³⁰ See Klindt, *supra* note 24, at § 19, margin numbers 1, 25.

³¹ See *id.* at § 20, margin number 4.

³² See Press Statement by the *Bundesministerium für Risikobewertung BfR* (Federal Institute for Risk Assessment) dated 29 December 2008, available at <http://www.bfr.bund.de/cd/27579>; see also *SÜDDEUTSCHE ZEITUNG* (South German Newspaper), no. 295, Dec. 19 2008, at 2.

³³ Editorial office of the *EuZW* with reference to Joachim Wuermeling, Undersecretary of State at the Federal Ministry of Economics, 18 *EuZW* 654 (2007).

Sicherheit, certified safety), which stands for tested product safety.³⁴ The GS mark can only be awarded by independent inspectors.³⁵

³⁴ This was also the recommendation of the *TÜV Rheinland* (Rhineland technical inspection agency) dated 18 December 2008, available at http://www.tuv.com/de/news_spielzeugrichtlinie.html?lan=1.

³⁵ See Geiß & Doll, *supra* note 24, at § 7, margin number 4.

