

# Product Safety Compliance - Current legal developments in Europe

SGS Juvenile Products Safety Forum 2022  
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## Presenter


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- Dr Arun Kapoor is specialized in the areas of product liability and product safety law. His clients include numerous national and international companies in various industries, both from the consumer goods and the capital goods sector. Dr Kapoor advises manufacturers and retailers on issues relating to product liability, product compliance and technical product regulation. He represents industrial clients both in and out of court in liability law disputes and in product-related administrative proceedings before German and European authorities.
- He also has comprehensive experience in the conceptual design and handling of international product recalls and in providing legal advice and support in product-related crisis situations.
- Dr Kapoor is the author of numerous academic and practice-oriented publications on product safety law and product liability law issues.

**Competences**

- Product liability law
- Liability and damages proceedings
- Product compliance and technical product regulation
- Product safety and technical law
- International product recalls
- Technical Compliance
- Claims for the recovery of recall costs
- International regulatory notification procedures
- Crisis and recall management
- Product safety law risk assessments (RAPEX)




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# Regulatory Framework

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## Regulatory Framework for juvenile products in Europe

**Applicability of European harmonization regulations – regulations to be considered**

- Toy Safety Directive**
  - Only applicable to product designed or intended, whether or not exclusively, for use in play by children under 14 years.
    - Juvenile products are often neither designed nor intended for use in play
- Other product-related harmonization regulations**
  - Low Voltage Directive, EMC Directive, RED, RoHS etc.
    - May be applicable to electronic juvenile products but usually not
- General Product Safety Directive (GPSD)**
  - Applicable to all kinds of consumer products, if no more specific product-related European harmonization regulation applies
    - Normally this is the governing legislation for juvenile products, however other non product specific regulation may also apply (e.g. Annex XVII REACH)




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## Basic safety requirements of the GPSD

- A product may only be made available on the market if it does not put the safety and health of persons at risk when used as intended or in foreseeable manner.
- In order to assess whether a product complies with the requirement pursuant to sentence 1, the following aspects are to be taken into account in particular:
  - the properties of the product, including its composition, packaging and instructions for assembly, installation, maintenance and useful life,
  - the impact of the product on other products, where it is reasonably foreseeable that it will be used together with other products,
  - the presentation of the product, its marking, any warnings, instructions for use and instructions for its disposal and any other product related data or information,
  - the groups of users that are exposed to greater risks than other groups.

- To assess compliance with the requirements, harmonised, non-harmonised and national standards may be considered
- Presumption of conformity if product complies with harmonised standards listed in the OJ




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## Further requirements of the GPSD

**Formal requirements**

- Provide safety information and instructions for proper use
- Affix of name and complete postal contact address of the manufacturer or importer (based in the EU)
- Provision of complaint and recall management
- Provision of complaint and recall management
- Obligation to notify national market surveillance authorities if manufacturers, importers or retailers know or ought to know that the product poses a risk to health and safety (RAPEX risk medium or higher)



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## / Safety requirements for consumer products (1)

### Abstract safety requirements for consumer products

- ▶ General safety requirement for consumer products
  - ▷ Consumer products must not endanger the safety and health of persons, when used as intended and in foreseeable manner.
- ▶ Presumption of safety: A product is presumed to be safe if it
  - ▷ complies with the requirements laid down in applicable European standards for the product or, if there are no such standards, if it meets the requirements of national standards
- ▶ If the presumption of safety does not apply (no standards available or product does not comply with these standards) the following aspects are to be considered for the safety assessment:
  - ▷ technical characteristics of the product,
  - ▷ packing,
  - ▷ instructions for assembly, installation or maintenance
  - ▷ presentation, labeling, warnings and safety instructions

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## / Safety requirements (2)

### Abstract safety requirements for consumer products (2)

- ▶ Consumer groups exposed to risk when using the product, especially vulnerable consumers such as children, the elderly and people with disabilities;
- ▶ The fact that a product, although not designed or suitable for children, is to be considered as attractive to or suitable for use by children;
- ▶ Cybersecurity features necessary to protect the product from external influences

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## / Alignment of the regulation with the New Legislative Framework

### What is the New Legislative Framework?

- ▶ The New Legislative Framework is the further development of the so-called New Approach of the EU for product regulation and conformity assessment. The New Approach dates from 1985 and is characterized in particular by the following:
  - ▷ Statutory requirements contain only abstract safety requirements that are specified by harmonized technical standards.
  - ▷ Placing products on the market does not require prior official approval. Market surveillance authorities are limited to reactive market control.
- ▶ The New Legislative Framework has been developing the New Approach since 2010 by implementing the following:
  - ▷ Standard definitions of important terms (e.g. placing on the market, making available on the market, manufacturer, importer, distributor etc.)
  - ▷ Standard catalog of obligations for economic operators with different obligations for manufacturers, importers, distributors and authorized representatives
  - ▷ Legal acts with the same structure based on "model provisions" from EU Commission Decision 768/2008/EC

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## / Online marketplaces

### New obligations for online marketplaces, Art. 20

- ▶ Online marketplaces are platforms that offer products from distributors based outside the EU and for which no economic operator is established in the EU. Online marketplaces are subject to new obligations:
  - ▷ Central contact address for market surveillance authorities in the event of complaints
  - ▷ Registration requirement for online marketplaces
  - ▷ Obligation to remove dangerous products from the marketplace within two working days of being requested to do so by the market surveillance authorities.
  - ▷ Obligation to publish certain information and product warnings on the marketplace upon request by the market surveillance authorities
  - ▷ Obligation to monitor the market and proactively block dangerous products

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## / New official reporting obligations

### Official reporting obligations for consumer products:

- ▶ Current official reporting obligation to the competent market surveillance authorities
  - ▷ Notification to the authorities if the economic operator knows or must know that a consumer product poses risks to the safety and health of persons.
  - ▷ In practice: obligation to notify if RAPEX risk assessment results in a „medium risk“ or higher
- ▶ In the future: Obligation to report accidents under the following conditions (Art. 19):
  - ▷ The manufacturer has become aware of an accident caused by a consumer product placed on the European market. Importers and distributors must inform the manufacturer in the event of an accident.
  - ▷ It is irrelevant whether the accident resulted in personal injury, what degree of contributory negligence the consumer has, or whether the consumer product poses a relevant risk as defined by RAPEX.

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## / Expansion of recall obligations for consumer products

### Recall must be associated with corrective action in the future

- ▶ Until now, economic operators (primarily the manufacturer) had to take appropriate hazard prevention measures if they knew or should have known that their products posed unreasonable safety risks in the field. The higher the risk to the safety and health of persons, the more intensive and far-reaching the protective measures must be.
  - ▷ For the recall as a hazard measure, it was specified that it is a measure aimed at ensuring that the affected product is returned to the manufacturer. The product safety directive does not regulate whether and to what extent the consumer must be compensated for this return.
- ▶ Going forward, consumers will have a right to effective, free, and timely remedies, which must include at least one of the following elements:
  - ▷ Repair of the recalled product;
  - ▷ Replacement of the recalled product with a safe product of the same type of at least the same value and quality;
  - ▷ Refund of the value of the recalled product.

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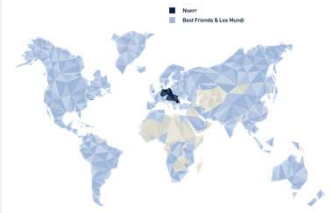


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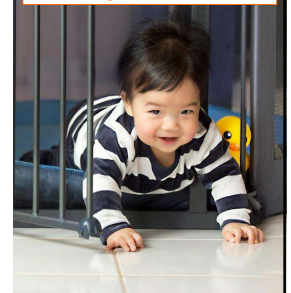
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