
Mai 2022

# PRACTICE GUIDE

## RISK MANAGEMENT & PRODUCT REQUIREMENTS

### CONTENT



### INTRODUCTION

Nothing ventured, nothing gained – entrepreneurial actions always entail certain risks. It is in the nature of things. However, it is the management's responsibility to deal with risks appropriately and engage in risk management. This mainly also involves detecting, evaluating and limiting legal risks.

These risks can occur in all areas of a company, especially when involved in the manufacturing, trading and distribution of products. Product safety requirements are continuously increasing. According to the German Federal Motor Transport Authority (KBA), 2019 was the year with the most product recalls, although 2013 was the year of the biggest food fraud of the 21st century (namely the horsemeat scandal) and in 2016, the world was talking about the "Dieselgate". Such headlines can damage your image and turnover. The management is liable – possibly also personally – if an unsafe or otherwise non-compliant product enters the market and violates legal interests. The **"principle of the general responsibility and competence of management"** [BGH (i.e. the German Federal Supreme Court), 06.07.1990, leather spray decision] applies generally – even if the management is split between several people and divisions.

**How to avoid liability? In short: Safeguard Product Compliance!** The obligation to do so arises from law. Managing directors and board members are bound by their employment contracts, by the Articles of Association and by law and statute. They **must act "*properly and diligently*"** (Sec. 43 German Limited Liability Companies Act ("**GmbHG**"), Sec. 93 German Stock Corporation Act ("**AktG**")) and carry out the **"*necessary*" supervisory measures** to prevent business-related misdemeanours and offences (Sec. 130, 30 German Act on Regulatory Offences ("**OWiG**")). What "*properly and diligently*" means, is based on the "*customary usage in the trade*".

However, when it comes to specific **guidance** and organisational guidelines, managers are left alone by the legislator and case law. We have developed this Practical Guide to illustrate how liability risks can be minimised by a business organisation based on best practice principles.

## RISK MANAGEMENT – PRINCIPLES

Risk management refers to the detection, evaluation, restriction and, if necessary, the outsourcing of risks.

Risks **must be detected as soon as possible**, if possible when alternative courses of action are still available. The obligation to possess an **early warning system** results from Sec. 91 II AktG. The controlling, audit and legal departments offer support with monitoring, analysis and reporting to the company management.

Risks must be **evaluated** and *"only entered into by sensibly weighing up the commercial interests"* (BGH, 03.12.2001, on bank lending). Risks are usually evaluated by assessing the worst case. The risk reviewed in this way is weighed up against the performance of the company and the expected profit along with the likelihood that it will occur.

Risks must be **restricted**. There is **room for manoeuvre** when it comes to addressing risks. However, this is "*exceeded when [...] the high risk of damage is irrefutable and yet there are no valid business reasons for addressing it*" (BGH, ibid.). Risks must therefore be avoided (exit from critical business segments), reduced or **outsourced** at least to a certain extent to other companies (suppliers, providers), insurance companies and banks (factoring, derivatives).

## BUSINESS ORGANISATION

Risk management may only be conducted successfully if managers have **the relevant information** at their disposal. This is already being called for by the **business judgement rule**, according to which executive board members must act on the basis of "*appropriate information*" when taking decisions (see Sec. 93 I 2 AktG).

The flow of information must be ensured by a corresponding business organisation. This applies all the more when delegating tasks and documenting this, which requires the observance of several rules.

### Communication & Information

The **communication** must function consistently from outside to inside and from bottom to top (from reception to boardroom, as it were). It is important to ensure that the information relevant for the management also reaches the management thanks to an organisational structure with clear tasks. This usually involves regular reporting on important facts to the management as best practice.

It is also necessary to ensure that **trade secrets are kept** (Sec. 93 I 3 AktG and Sec. 85 I, II GmbHG), e.g. by restricting the forwarding of information to certain persons / departments (what is referred to as *Chinese Walls*). This applies in particular to insider information (Sec. 13 et seq. German Securities Trading Act ("**WpHG**")). The cooperation with lawyers also involves **protecting information**, because the communication is subject to professional secrecy (the **"attorney-client privilege"** applies both to inside and outside counsels).

### Delegation & Control

The larger the company, the more duties are delegated. The following **principles** apply for **delegation**:

- Do not fully delegate all duties. The management function shall remain with the board (see Sec. 76 I AktG: "*The Executive Board is responsible for managing the company*", BayObLG (Bavarian Highest Regional Court), 10.08.2001: „*Sec. 130 I 2 OWiG expressly obliges the business owner to also monitor the supervisors"*).
- Establish a clear and precise delegation without overlaps:
  - avoid gaps in responsibility and dual responsibility (= not *"everybody relies on everyone else"*; see OLG (Higher Regional Court) Düsseldorf, 12.11.1998);
  - if necessary, replacement / back-up personnel for the event of an impediment (BGH, 17.10.1967, on defective thrust rods, relating to replacement for product test).
- Delegate obligations to employees only who
  - are selected properly depending on the task and importance,
  - are competent,
  - are instructed and inducted or guided under supervision,
  - are kept informed and
  - have the means to fulfil their duties (see OLG Düsseldorf, 25.02.1990).
- Adapt, if necessary, the organisation of delegation to the quality management system (if necessary: reflecting the company).
- Announce document delegation within the company.
- Monitor delegation for compliance, namely with "*at least random surprise inspections*" (BGH, 24.03.1981 on cartel violations of the tendering department). If spot checks are not sufficient, "*more extensive surprise company inspections*" must be performed (BGH, 25.06.1985, on bridge construction).

### Documentation & Proof

The following must be **documented**:

- the company organisation including risk management,
- decisions that entail a greater risk,
- all measures for avoiding liability (such as quality management),
- the delegation of tasks, and
- generally also all other procedures that may relate to liability.

After all, this documentation helps with your own **monitoring of risk management.** It is also possible to use this to **prove in court** that the necessary precautionary measures have been taken and that you have acted "*properly and diligently*". This helps, in turn, to avoid liability – because the burden of proof rests with your company (for legal action resulting from product and producer liability) and with the management (for liability suits against the management).

## SUPERVISORY DUTY OF MANAGERS

Managers and employees must not commit **any legal violations** (Sec. 9, 30 OWiG). Managers must also conduct themselves in a lawful manner by virtue of their management function ("**principle of legality**").

Furthermore, managers must exercise "*proper supervision*" to **prevent their employees from committing legal violations.** Otherwise, even a slightly

negligent breach of the supervisory obligation may result in **fines** (Sec. 130 OWiG). This supervisory obligation forms the lowest threshold of supervisory obligations in the company. The statutory regulation is couched in very general terms. It has not even been clarified whether the supervisory measures relate solely to the company alone or to group subsidiaries as well. While the BGH has doubts (cf. BGH, 01.12.1981, on mixed concrete), the BKartA (i.e the German Federal Cartel Authority) considers the managers of a holding to be subject to a supervisory obligation even in the case of cartel infringements committed by subsidiaries. A double-digit million fine has already been imposed in the case of price agreements due to a violation of the supervisory obligation (BKartA, 09.02.2009, on roof tiles). **Managers are also personally liable towards their company** if they violate their duty of care (Sec. 93 II AktG and Sec. 43 II GmbHG).

It is therefore **important** to have an **overview of the numerous legal product requirements** in order to organise the company accordingly and to better coordinate the supervising tasks.

## PRODUCT SAFETY – SAFETY FIRST

Risk management can be defined even more specifically for individual company divisions. Risks may occur in relation to product safety. These risks are best minimised by managing them systematically along the supply chain and during the whole life cycle of a product from development to after sales.

Manufacturers have to manufacture their products in a way that ensures they are safe, i.e. ideally, nobody can get injured when using or being exposed them. At the same time, products necessarily expose certain risks, some even in order to fulfill their function in the first place: For example, every knife has a cutting edge that poses a risk of injury. Therefore, "*the **consumer** can**not expect complete safety***." However, "*measures must be taken which are objectively necessary according to the circumstances of the case in question to avoid and eliminate a risk and which are feasible in accordance with objective standards*" (BGH, 17.03.2009, on the production of cherry biscuits). The underlying principle is: **the greater the risks, the higher the requirements**.

If these abstract requirements are not adhered to, this is attributable to the management. In other words, the flipside of an unsafe product is the risk of a claim based on product liability. Under German product and producer liability law, even the management is (possibly also personally) liable if a defect product enters the market and violates legal interests. To prevent liability as well as measures of a competent authority and to safeguard the reputation of the company, the management must ensure that the necessary and feasible product safety requirements are adhered to at every stage of the life cycle. The life cycle of a products starts with the development of the product and does not even end in the case of recalls – a conceivable broad concept. In short words: It is all about "**product safety management**". Insofar, organizational measures to handle the broad approach are crucial. In this context, the delegation can also play a role when a "*product safety officer*" is appointed to monitor product safety.

Below, we would like to give you a brief overview on some specific sales and after sales relevant requirements of selected statutory product regulations.

## PRODUCT COMPLIANCE – FUNDAMENTALS

**Product compliance related regulations exist on three levels: product safety law, product as well as producer liability law and "product criminal law".**

### Product Safety Law

Product safety law contains **detailed requirements** in relation to design, production, placement on the market and product monitoring. The regulations briefly described in the following have in common that they set up framework-like basic principles and then mostly refer to detailed regulations (often "Harmonized Standards"), which also set up concrete technical requirements.

In the **non-food** sector, basic principles are governed by the German Product Safety Act ("ProdSG"), whereby for certain products as vehicles, medicinal products, medical devices, or cosmetics further basic regulations (partly additional) apply. Applicable to **food and consumer goods**, on the other hand, is the Foodstuffs, Consumer Goods and Feedstuffs Code ("LFGB").

Following the approach described above, Sec. 3 I ProdSG stipulates rather abstract that a product can only be sold if its "*intended or expected use does not endanger the safety and health of persons"*.

Besides that, product safety law lays down the basis for **competent authorities** to **intervene** if they suspect **non-compliant products**.

### Product as well as Producer Liability Law

Product and producer liability law governs whether a company and/or its management are **liable for** damages due to a **defect product** or because of the **violation** of **due diligence obligations**.

Claims under the German **Product Liability Act** (ProdHaftG) rely on harmonised law. Similar regulations apply throughout the European Economic Area ("**EEA**") because they are based on the same EU Directive 85/374/EEC of 25.01.1985. Claims under producer liability law are based on national tort law, in Germany Sec. 823 I of the German Civil Code ("**BGB**") forms the basis.

**Product liability** is **regardless of culpability**. Conversely, compensation is capped at EUR 85 million (for the same event). Even the mere importer of a product is deemed a 'producer' and can therefore be liable. On the opposite, **producer liability depends on culpability**, but does not provide for a maximum liability amount. Importers are not liable on basis of producer liability.

The liability-forming terms "product defect" and "due diligence obligation" are basically the flip side of the same coin. **Product defects** respectively **due diligence obligations** exist in relation to **construction**, **production**, **instruction** and **market observation** (the latter from producer liability perspective). Companies and management are liable if, due to a product, a person is

killed, injured or his property is damaged. In the field of product liability, In favor of the injured party, simplifications to proof a defect and fictions are made. For example, the culpability is assumed but can be disproved or liability is excluded if a "development defect" is present. The latter requires that the manufacturer proofs that the defect was not evident when the product was placed on the market and the product complied to the state of the art in science and technology at that time (BGH, 16.06.2009, on airbags).

Besides that, customers may also assert **warranty claims** against their suppliers beyond the actual product liability law. This is as the warranty obligation provides for another understanding of "defect" which, however, often leads to the same result: An unsafe and therefore "defective" product according to product liability is usually defective according to warranty obligations (unless an agreement has been reached on its unsafe condition). Warranty claims include the delivery of a defect-free object or subsequent performance, reduction, rescission and, in the event of culpability, compensation for damages. Culpability often rests with the manufacturer, but not necessarily with the trader. The trader does not usually have to take responsibility for the culpability of the manufacturer either (BGH, 02.04.2014, on wooden windows).

### "Product criminal law"

In the *worst case*, i.e. if people are actually injured or even die as a result of defective products (Sec. 212, 223 et seq. German Criminal Code ("StGB")), this may lead to fines and imprisonment (and criminal investigation measures beforehand, e.g. dawn raids). These are not directed at the company, **but at the responsible persons**, i.e. the management (see Sec. 9 OWiG, Sec. 14 StGB and BGH, 06.07.1990 product related obligations of a managing director).

Corresponding investigations by public prosecutors are often initiated by criminal complaints that are filed to collect/preserve evidence for subsequent claims for damages. **The most famous cases** are thalidomide (drug), Monza Steel (car tyres), Erdal Rex (leather spray) or the wood preservative case (PCP and lindane materials) – **products from all segments.**

Product safety law also provides for **fines** in numerous instances if product safety requirements are not adhered to (Sec. 39 ProdSG), e.g. if

- manufacturers of consumer products do not attach their contact details to the product,
- the required instructions are not available in German or
- the required CE marking is missing.

If certain violations are "*persistently repeated*" or life, health or objects of significant value are put at risk, the offender can also expect a **prison sentence** (Sec. 29 ProdSG).

Regardless of this, **damage may occur to a company's reputation** (as a kind of further punishment) if defective products are brought to the market and sold. For all of these reasons, it is important for manufacturers, distributors and all other economic operators to be aware of the legal requirements and to bring the company organisation into line with them.

## PRODUCT SAFETY – GUIDELINES

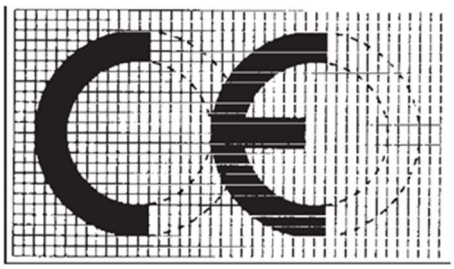
As a general rule, companies may only sell safe products that in particular do not put the health and safety of persons at risk (Sec. 3 ProdSG).

### EU product safety requirements

Additional and/or separate requirements exist for certain product categories through EC/EU harmonisation legislation. The following is a non conclusive lists covering especially relevant products.

- Electrical equipment with low voltage (Directive 2014/35/EU),
- Toys (Directive 2009/48/EC),
- Simple pressure vessels (Directive 2014/29/EU),
- Gas appliances (Regulation (EU) 2016/426),
- Personal protective equipment (Regulation (EU) 2016/425),
- Machinery (Directive 2006/42/EC),
- Recreational craft and personal watercraft (Directive 2013/53/EU),
- Equipment and protective systems in potentially explosive atmospheres (Directive 2014/34/),
- Lifts (Directive 2014/33/EU),
- Aerosol dispensers (Directive 75/324/EEC)
- Pressure equipment (Directive 2014/68/EU),
- Construction products (Regulation (EU) 305/2011),
- Electromagnetic compatibility (Directive 2014/30/EU),
- Radio equipment and telecommunications terminal equipment (Directive 2014/53/EU),
- Ecodesign of energy consuming products (Directive 2009/125/EC),
- Explosives for civil uses (Directive 2014/28/EU),
- Pyrotechnic articles (Directive 2013/29/EU),
- Equipment and machinery for use outdoors relating to noise emissions (Directive 2000/14/EC),
- Hot-water boilers (Directive 92/42/EEC),
- Measuring instruments (Directive 2014/32/EU),
- Non-automatic weighing instruments (Directive 2014/31/EU),
- Cableway installations designed to carry persons (Regulation 2016/424),
- Medical Devices and in-vitro diagnostics (Regulation (EU) 2017/745 and Regulation (EU) 2017/746).

For all products covered by these directives, there is the obligation to assess conformity of and affix the CE marking to these products.



However, the EU laws only govern the **general, fundamental** safety and health **requirements**.

**Technical details are governed by harmonised standards** (e.g. certain standards "*EN* ..." and "*DIN EN* ..." insofar they are approved by the EU).

### Harmonized Standards

Designing and manufacturing according to harmonized standards is not

mandatory but often advisable as compliance with harmonized standards leads to **presumption of conformity** (cf. Sec. 4 ProdSG): if a product is compliant to the respective harmonized standard, it is presumed that the legal safety requirements are also complied with. The product is thus generally marketable.

Additionally, a number of voluntary – national – standards or technical specifications for products for which no EU safety requirements are existant. The **presumption of conformity** also applies here (Sec. 5 II ProdSG).

### Achieving Marketability

Manufacturers and other economic operators often find the jungle of framework-regulations, laws and (harmonized / other technical) standards confusing. However, adhering to these provisions is the way to distribute products throughout the whole EEA.

Furthermore, neither manufacturers nor other economic operators are left alone: **Overviews** on the European product law system as well as on German and European harmonized / technical standards can be found

- in the "Guide to the implementation of directives based on the New Approach and the Global Approach" (the **"Blue Guide")** and
- on the webpage of the "Baua", i.e the German Federal Institute for Occupational Safety and Health.

### Additional requirements for consumer products

Additional requirements exist for consumer products (**B2C products**). These are products that are intended for consumers, used predictably by consumers or made available to the consumer as part of a service. Their counterparts are industrial products (B2B products) – see above for their requirements.

The additional obligations for consumer products are mainly of a formal nature. A distinction is made between:

**1. Pre-market obligations**
("*upon provision*")

- Risk information (supplements the instructions), Sec. 6 I No. 1 ProdSG,
- Manufacturer information (if possible on the product), Sec. 6 I No. 2 ProdSG,
- Product traceability (e.g. through type/serial numbers), Sec. 6 I No. 3 ProdSG.

**2. Post-market obligations**
("*for products provided*"):

- Risk prevention and recall management, Sec. 6 II ProdSG,
- Product monitoring, complaint investigation, trader information, Sec. 6 III ProdSG,
- Information to the market surveillance authorities, Sec. 6 IV ProdSG.

The obligations primarily aim at **manufacturers**. **However,** other economic operators as importers, distributors and even fulfilment service providers might also be affected by these provisions, especially according to the new European Regulation on Market Surveillance (Regulation (EU) 2019/1020, "MSR") **Distributors** have to fulfil their "**due diligence obligations regarding the care in sales**": they must contribute to ensuring that only safe consumer products are placed on the market. Products that do not comply with product safety requirements may not be sold (Sec. 6 V ProdSG; cf. OLG Munich, 11.12.2014, Sales ban on headphones). This means that distributors should inspect the delivered products accordingly to avoid sales bans.

### From Warnings to Recalls

Warnings involve instructing customers and notifying authorities (sometimes also referred to as "*self-denigration*"). Whether a warning is sufficient or a further measure – as a recall – has to be carried out by the manufacturer can be determined on basis of the following table.

**What must be done?**

Inform about the need of a certain way of use, an upgrade or reparation,

- if necessary, offer help,
- request the non-use or decommissioning of dangerous products,
- if applicable, recall products to prevent them from being used dangerously.

Inform on the content, scope and time depend on the legal interest at risk and the extent of the danger. It is important to have consistent product communication.

**How long?** The security obligations of the product manufacturer "*do not end [...] when the product is placed on the market [...]. Instead, the manufacturer, even after this time, must do everything reasonable under the specific circumstances to avert risks which its product may cause*" (BGH, 16.12.2008, on nursing beds).

**When?** *"Risk to the health and safety of persons"* (for consumer products see Sec. 6 IV 1 ProdSG) or a combination of the probability of occurrence and severity of damage, see RAPEX Guidelines of the EU Commission (decision (EU) 2019/417 of 08.11.2018, repealing the previous version of 16.12.2009).

**Level of risk as result of the combination of severity and probability**

| Probability of a damage during the expected durability of the product | | Severity of the damage | | | |
|---|---|---|---|---|---|
| | | 1 | 2 | 3 | 4 |
| High | > 50% | H | E | E | E |
| | > 1/10 | M | E | E | E |
| | > 1/100 | M | E | E | E |
| | > 1/1 000 | N | H | E | E |
| | > 1/10 000 | N | M | H | E |
| | > 1/100 000 | N | N | M | H |
| | > 1/1 000 000 | N | N | N | M |
| Low | < 1/1 000 000 | N | N | N | N |

E – Serious risk
H – High risk
M – Medium risk
N – Low risk

## RECALL MANAGEMENT: 5 SPECIFIC ACTION STEPS

**Recall management does not start with the recall itself. Set up monitoring processes for products in the field in advance and define how you will determine whether a product needs to be recalled at all.**

1. **Investigating the facts – identify the "root cause"**
   - Technically: where lies the incompliance? what is affected, the entire series or just a batch?
   - Sales: where can the products be found?
   - Legally: which recourse possibilities exist?
2. **Establishing the ad-hoc recall team**
   - Decides centrally,
   - Includes representatives of all departments.
3. **Recall planning**
   - Specific technical solution,
   - Logistical planning,
   - Legal preparation of the notification,

- Corporate communications.

4. **Carrying out the recall**
5. **Identifying and making contributions to the cause:**
   Are the lessons learned?

## DEFENCE AGAINST OFFICIAL MEASURES

Market surveillance authorities can take "*necessary measures*":

1. **Preliminary measures, e.g.:**
- Review in the company,
- Product test (Art. 11 III MSR).

2. ***Market surveillance measures*** according to Art.14 et seq. MSR such as:
- (Final) prohibition of provision, Recall order (Art. 16 III, V MSR),
- official warning (Art. 14 IV (k) MSR),
- demand disclosure of relevant documents (Art. 14 IV (a) MST)

**How do you defend yourself against this?**

To our experience, the best way to solve issues raised by authorities is a safe and sound approach regarding the communication with the competent authority.

If the authority nevertheless issues officials acts like a so called administrative act, the **objection** (if admissible, or **provisional legal protection**) and then (or sometimes directly, such as in Bavaria) **action for annulment** before the administrative court help as defence measures in seeking to have the administrative act repealed.

An administrative act may also be completed through "compliance": the authority revokes / changes the measure as soon as the economic agent proves that it has taken effective measures.

## MARKET SURVEILLANCE

**On 16 July 2021**, the European Regulation on Market Surveillance (Regulation (EU) 2019/1020, "MSR") came into full force. It is aimed at stepping up the efforts to keep non-compliant products out of the European single market, through a **stronger and more effective market surveillance** and clearer rules, a more rigorous control of compliance and a closer cross border cooperation of the authorities.

**What is affected?**

**All products entering the market** of the EEA from outside the EEA are governed by the MSR respectively MSR's provision on product controls by authorities before such products are released for free circulation within the EEA (Art. 25 – 28 MSR).

Besides that, the MSR basically applies to a **large proportion of B2C products and B2B products manufactured within the EEA**. Products covered are those that fall under the harmonisation legislation listed in Annex I of the MSR. The MSR obeys a holistic approach: Not only regulations on product *safety*, but also regulations on product-related *environmental law*, such as the WEEE Directive are cited there meaning that not only products which fall under a "CE labelling requirement" are governed by the provisions of the MSR.

Two **exceptions** to the scope of the MSR are noticeable: Firstly, **more specific regulations under product safety law take precedence** insofar as these regulations themselves establish more specific provisions than the MSR does (e.g. medical devices, type approval requirements). Secondly, the **MSR is a "non-food" regulation**. In particular, products covered by the regulations on food, feed and medicinal products do not fall within the scope of application.

**What are the main changes?**

Significant changes in connection with the above said product categories relate in particular to the fast-growing areas of e-commerce and global supply chains.

As regards the **e-commerce**, the MSR broadens the definition of "*placing on the market*": a product shall now be deemed to be made available on the market if the offer is targeted at end users in the EU, online or through other means of distance selling. This must be assessed on a case-by-case basis, depending on whether the offer of the product is actually aimed at the EU internal market, which can be derived e.g. from the possible supply regions, the available languages or the payment methods.

Furthermore, the MSR also extends the links in the **supply chain**: they now include the so-called "*fulfilment service provider*", defined by the Regulation as "*any natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved*".

**Who is affected?**

Potential addressees of market surveillance measures are the persons known as "**economic operators**": Manufacturer, authorized representative, importer and distributor. In addition, the MSR expands the circle of addressable economic operators: on the one hand by **adding the fulfilment service provider**, on the other hand by adding any person who is subject to obligations in relation to products (e.g. their manufacture or their market availability).

**What must be done?**

Regarding many products governed by a "CE-labelling requirement", the MSR defines a further marketability requirement which hast to be fulfilled before these products may be placed on the market: To establish a contact person for market surveillance authorities, an economic operator responsible for certain tasks (such as keeping and providing documentation, notifying high-risk products, labelling its name on the product) has to be existent. Potential contact person may be one of the following economic operators: manufacturer, importer, authorized representative or fulfilment service provider.

### MSR & ProdSG

With the MSR, the ProdSG was rewritten, especially shortened. Main content of the ProdSG are now product safety related marketability requirements. Besides the ProdSG, the German law now provides (i) for a Market Surveillance Act ("**MüG**") which covers all products and (ii) for Act on Installations Requiring Surveillance ("**ÜAnlG**") which covers certain installations, at the moment those governed by Section 2 XIII German Regulation on Industrial Safety and Health ("**BetrSichV**").

## ENVIRONMENTAL LAW – REACH

REACH stands for **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals. The REACH Regulation is the European Chemical Law, applicable since 2007. It follows the principle "*no data, no market*", requesting that market players (aside from consumers) obtain and register the safety-related data on the material properties (physical properties, toxicity, behaviour in the environment, etc.) themselves (and at their own expense). The recorded substances and products may not be sold without being **registered**.

**Who is affected?**

Anybody who **purchases, manufactures** or **uses chemical substances** in any form that are produced in quantities of at least 1 tonne per year ("t/a") in the EEA or are imported into the EEA is affected by REACH.

Waste and radioactive substances, in particular, are excluded from the REACH obligations. Also excluded, under further conditions, from certain obligations, e.g. of registration, are: polymers, substances used in medicinal products for humans and animals, substances in the food or animal feed sector, active substances in plant protection and biocidal products, reimports of already registered substances and substances for research and development. There are predominantly **special regulations** in the corresponding European legal acts for these substances and their national implementation.

**What obligations exist?**

There is an extensive **registration requirement** as well as the obligation to provide **test data** and **test proposals** from certain quantity thresholds.

Manufacturers in or importers to the EU of substances in quantities of one t/a or more or of articles with substances intended to be released in the same quantities must register those substances with the European Chemicals Agency ("ECHA") by submitting a technical dossier detailing all physicochemical and toxicological properties of the chemicals involved and the safety measures required in handling them.

For substances contained in products that are imported or manufactured in quantities of more than 10 t/a, a **Chemical Safety Report** ("CSR") including exposure scenarios is also required for successful REACH registration.

The ECHA reviews all REACH registration documents and may request additional information, if deemed necessary.

Producers or importers of articles may need to notify the ECHA if there are any **Substances of Very High Concern** ("SVHC") in said articles above a concentration of 0.1% by weight. SVHCs require an authorization. The list of substances subject to authorization is regularly updated, currently counts 211 elements and includes the ones falling into the following categories:

- CMR (Carcinogenic, Mutagenic or Toxic to Reproduction)
- PBT (Persistent, Bioaccumulative Toxic)
- vPvB (Very Persistent and Very Bioaccumulative)
- Substances of equivalent concern with scientific evidence of probable serious effects

Authorization may only be granted if there are no suitable alternative substances or technologies available and if the social and economic benefits outweigh the risks.

EU member states may propose **restrictions** on the manufacturing, marketing and use of certain dangerous substances and preparations. These may be subject to EU-wide restrictions if their use poses unacceptable risks to health or the environment (as per Annex XVII REACH).

Since **31 December 2019**, new rules apply to **phase-in substances**, namely substances that were already being manufactured or placed on the market before the entry into force of the REACH Regulation. After the elapsing of the transitional regime provided for them (allowing a later registration and calculation of annual tonnage based on a three years average), now the following rules apply to phase-in substances.

- The production/import volume calculation methods based on the three years average will not apply any more, instead the volume calculation will be based on the calendar year.
- Already submitted pre-registrations are no longer valid and potential registrants shall follow the inquiry process set out in Art. 26 of the REACH Regulation.
- Phase-in substances in the 1–10 tonnage band range that do not meet the criteria set out in Annex III of the REACH Regulation will continue to benefit from the less stringent information requirements (as per Art. 12 of the same Regulation).

**Who is obliged?**

The obligations generally affect the **manufacturer**. However, if the manufacturer does not reside in the EEA, it can register the substance in the EEA through a "*sole representative*".

If there is no sole representative, all obligations affect the **importer**. The importer is anybody who is responsible for importing substances and therefore also a further processing company or even an **end consumer**.

**Consequences of a violation**

If in breach of the REACH Regulation, the product cannot be distributed and therefore may not be placed on the market. In addition to substantial fines and official measures relating to manufacturing and distribution, there is also the risk of chargeable cease-and-desist letters from competitors.

Further information can be found on the websites of the ECHA and of the Federal Environmental Agency ("UBA").

## SCIP DATABASE

Since **5 January 2021**, any suppliers of articles (defined as "*an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition*" by art. 3 no. 3 of the REACH, thus ranging from a screw to a complex article such as an engine or an electronic device) on the E market will be required to notify the **ECHA** if their articles contain Substances of Very High Concern ("SVHC") above 0.1% by weight (w/w). The ECHA was tasked with creating and maintaining the public **SCIP database** (Substances of Concern In articles as such or in complex objects (Products)) for this purpose. SCIP notifications can be submitted to allow the suppliers sufficient time to be compliant for the January deadline.

The minimum information which a supplier needs to submit in a SCIP notification consists of the following:

- information that allows the identification of the article;
- identification of the candidate list substance in the article, its concentration range and its location, as appropriate; and
- possibly, any other information on the safe use of the article, available to the supplier, e.g. information which is necessary to ensure proper management of the article once it becomes waste.

**Who is obliged?**

A supplier who has the responsibility to submit SCIP notifications is called a **duty holder**. A duty holder is a natural person or a legal entity in the E who supplies articles on the E market, including:

- producers and assemblers,
- importers,
- distributors of articles and other actors who place articles on the market.

Retailers who are not simultaneously importers and/or producers, and other supply chain actors supplying articles directly and exclusively to consumers are not covered by the obligation.

While non-E persons or legal entities have no direct obligations to fulfil this new requirement, they can submit SCIP notifications directly on behalf of a duty holder in the EU who has appointed them as a foreign user for this obligation.

## CONFLICT MINERALS

Conflict minerals and conflict commodities are commodities that come from regions with warlike conflicts. It is often suspected that the conflicts will continue to be financed by these commodities.

Since 2012, companies in the USA have been required to report to the Securities and Exchange Commission ("SEC"), i.e. according to **Section 13 (p) of the US Securities Exchange Act of 1934** (amended by the "*Dodd-Frank Act*" = "*Wall Street Reform and Consumer Protection Act*" of 2010). Accordingly, reporting obligations exist if *conflict minerals* are required for the functionality or manufacture of a product. The reporting obligations relate to the origin of the commodities.

**Conflict minerals** are columbite-tantalite (coltan ore), cassiterite (tin ore), wolframite (tungsten ore) and gold (sometimes also referred to in English as "***3 T** (Tantalum, Tin, Tungsten) **plus Gold"*** (3TG) due to the elements behind it. Details are in flux, as the implementation is governed in detail by the SEC (*inter alia* in a 356-page Final Rule, etc.).

**For purchasing**, this means: it is best to ensure that no conflict minerals are purchased – this can also be achieved with corresponding regulations in the **general terms and conditions of purchase**. You can stipulate a corresponding **clause** close to the US regulation, provide a guarantee from the supplier that it does not supply any conflict minerals or that they do not come from conflict countries (even if guarantees in the general terms and conditions are always critical), obligate the supplier to provide certificates that confirm adherence to the rules, stipulate control and information rights of the buyer and, if applicable, stipulate a flat-rate compensation or an indemnity obligation.

The **EU**, in turn, has also taken legislative action and published in 2017 the Regulation (EU) 2017/821 on Conflict Minerals ("RCM") laying down supply chain due diligence obligations for Union importers of tin, tantalum and tungsten, their ores, and gold originating from conflict-affected and high-risk areas. The obligations for EU importers to fulfil **due diligence obligations** in the supply chain, are laid down in Art. 3 I, II, IV-VII RCM (obligations relating to the management system, risk management obligations, obligation to carry out inspections by third parties, disclosure obligations) and **apply since 1 January 2021**, date of entry into force of the RCM. Importers have to prove that they obtain the minerals and metals covered by the RCM only from responsible sources. Excluded from the RCM are existing EU stocks created before 1 February 2013 as well as small import quantities and recycled metals. Please adjust in good time.

The obligations mainly impact upstream companies (miners, traders and smelters/refiners), since component producers, manufacturers and end users are excluded by scope of application of the RCM. However, this will be reviewed by January 2023 and after every triennium thereafter.

Apart from this, conflict minerals also play a role in purchasing for **corporate social responsibility** reasons.

## ENVIRONMENTAL LAW – CLP

CLP stands for "**c**lassification, **l**abelling and **p**ackaging". The CLP Regulation supplements REACH. It governs the classification, labelling and packaging of **hazardous substances**. This was previously done based on the EU Directives for hazardous substances and dangerous preparations (identifiable by the black hazard symbols on an orange background). Hazardous *substances* have to be identified according to CLP since 1 December 2010, *mixtures* (combinations of numerous substances) since 1 June 2015.

**What and who are affected?**

CLP must be adhered to when **producing, importing or delivering** substances (or mixtures) which are "hazardous". Whether a substance is hazardous solely depends on the criteria for physical, health or environmental risks in Annex I, Parts 2-5 of CLP. It does not depend on the amount of the substance manufactured or to be delivered.

**What obligations exist?**

The obligations of a company depend on its role in the supply chain. *Manufacturers, importers and downstream users* (i.e. persons who use the material for industrial or commercial purposes, but not traders) must **classify, label and package** hazardous substances pursuant to CLP – *traders* label and package the substances.

The Commission Regulation (EU) 2017/542 has added Annex VIII to the CLP Regulation. The new Annex VIII entered into force on 12 April 2017, and is applicable to mixtures for consumer use and to mixtures for professional use since **1 January 2021**, and will apply to mixtures for industrial use from **1 January 2024**. Annex VIII sets out provisions to harmonize, in terms of format and content, the information relating to emergency health responses that companies placing hazardous mixtures on the EU market are required to submit to the bodies appointed by each Member State (i.e. the "*appointed bodies*"). The required information includes i.a.

- the clear identification of the mixture and of the economic operator responsible for the placing on the market,
- information on the composition and hazardous ingredient substances and
- information on the intended use through a system of harmonized categories.

This information must be submitted by electronic means in a specified format, which enables the appointed bodies to easily retrieve the relevant information.

A **unique formula identifier** ("UFI") will allow the poison centers to univocally identify the mixture and propose the appropriate medical treatment in the event of poisoning.

The amended CLP Regulation provides that ECHA specifies the harmonized format (i.e. **Poison Centers Notification** ("PCN") format) for the preparation of information by economic operators. The PCN format also aims to facilitate the management and use of the submitted information by authorities and poison centers, who will receive the information and make it available in a database serving the emergency health response purpose. Additionally, according to Annex VIII, ECHA shall facilitate the submission of information. For this purpose, ECHA has made available a centralized **Submission Portal**, which could be used as an alternative to the national submission systems where available (it is at the discretion of each Member State to indicate which system is to be used).

### Consequences of a Violation

Apart from fines, official measures may be imposed along with civil liability in the event of damage.

### Special Rules

Special rules for the **transport of dangerous substances** are mainly governed by the national Regulation on the Transport of Dangerous Goods by Road, Rail and Inland Waterways.

## ROHS – DIRECTIVE 2011/65/EU

ROHS stands for "**r**estriction **o**f the use of certain **h**azardous **s**ubstances in electrical and electronic equipment". The RoHS Directive stipulates the provisions for the restriction of the use of hazardous substances in electrical and electronic equipment in order to make a contribution towards protecting human health and the environment including the environmentally sound recovery and elimination of waste electrical and electronic equipment.

**What is affected?**

The directive applies to electrical and electronic equipment in the following categories:

- Large household devices
- Small household devices
- IT and telecommunications devices
- Entertainment electronics devices
- Light fittings
- Electrical and electronic tools
- Toys as well as sports and leisure equipment
- Medical equipment
- Monitoring and control instruments including industrial monitoring and control instruments
- Automatic output devices
- Other electrical and electronic equipment

**What obligations exist?**

Electrical and electronic equipment that is placed on the market including cables and spare parts for repair may only contain the following substances in the specified maximum concentration (percent by weight):

- Lead (0.1%)
- Mercury (0.1%)
- Cadmium (0.01%)
- Hexavalent chromium (0.1%)
- Polybrominated biphenyls (0.1%)
- Polybrominated diphenyl ethers (0.1%) and, as later provided by the Commission Delegated Directive (EU) 2015/863, also
- Bis(2-ethylhexyl) phthalate (0,1 %)
- Butyl benzyl phthalate (0,1 %)
- Dibutyl phthalate (0,1 %)
- Diisobutyl phthalate (0,1 %).

**Who is obliged?**

**Manufacturers, importers and distributors** must adhere to the directive.

### Consequences of a violation

A violation of the ROHS Directive entails a legal offence which can be punished with fines up to EUR 100.00,00 according to Sec. 14 ElektrostoffV, i.e. the German regulation implementing ROHS.

## RED – RL 2014/53/EU

RED stands for **R**adio **E**quipment **D**irective. The RED has been valid for all electrical and electronic devices that deliberately emit and receive radio waves at frequencies under 3000 GHz since June 2016. RED replaced the no longer in force EU Directive on Radio and Telecommunications Transmission Equipment (R&TTE, 1999/5/EC).

**What is affected?**

The RED sets the essential requirements for health and safety, electromagnetic compatibility and the efficient use of the radio frequency spectrum in a single market for radio equipment. It also provides for technical features for the protection of privacy, personal data and against fraud, as well as additional aspects covering interoperability, access to emergency tools, and compliance with regard to the combination of radio equipment and software.

In addition to the devices that fell under

the R&TTE Directive (i.e. all radio equipment that may communicate in the spectrum allocated for terrestrial/satellite-based radio communication by radiation and/or receiving radio waves), the RED also covers TV sets, radios and devices below 9 kHz.

**Not falling under RED** are:

- (wired) fixed network terminal equipment (subject to the Directives 2014/30/EU and 2014/35/EU since 2014), and
- the radio equipment explicitly excluded in Annex I of the RED, such as radio equipment that is used by radio amateurs, marine equipment, airborne equipment as well as equipment for military, police and state-security and trial modules that are solely used for research purposes.

**What obligations exist?**

Radio equipment must meet the following fundamental requirements (cf. art. 3 RED).

- It must ensure the **protection of the health and safety of humans, animals and livestock and the protection of goods**. Annex I of Directive 2014/35/EU contains a summary of the most important information on these safety targets.
- It must provide for an **appropriate level of electromagnetic compatibility**, which is defined as follows in Annex I of Directive 2014/30/EU:
  - Equipment must be designed so that (a) the electromagnetic interference it causes does not reach a level at which radio and telecommunications devices or other equipment cannot be operated as intended and (b) it has a level of immunity to the electromagnetic disturbances to be expected in its intended use, which allows it to operate without unacceptable degradation of its intended use.
  - Fixed installations must be installed according to the recognised rules of engineering.
- Radio devices (or "apparatus") must be manufactured so that radio frequencies can be used effectively and the efficient use of radio frequencies is supported.
- They must be compatible with accessories (e.g. charging cables) in certain categories or classes, work together with other radio equipment via networks, be connected to one another via interfaces and must not have a harmful effect on the network or how it functions. They must have safety devices that protect the user's personal data and privacy and should contain certain functions for protection against fraud.
- Radio equipment types must also be registered in certain radio equipment categories affected by a low level of compliance with the above mentioned essential requirements since 12 June 2018.

**Who is obliged?**

**Manufacturers** are primarily bound by the RED. Aside from manufacturers, importers and distributors are also subject to certain obligations.

### Consequences of a violation

The consequences of a violation are not governed in the RED itself, but need to be implemented into national law. In Germany, the RED was incorporated into the **Radio Equipment Act ("FuAG"),** which came into effect on **4 July 2017.** According to this act, the Federal Network Agency (BNetzA) may ask the economic operator concerned to take appropriate measures to meet the legal requirements or recall the radio equipment (Sec. 24 FuAG) if it comes to the conclusion that the radio equipment is non-compliant and/or puts the health and safety of people or other protected assets in the public interest at risk. The BNetzA may impose fines **of up to EUR 500,000.00** for enforcement purposes (Sec. 34 FuAG).

The BNetzA may also request appropriate measures if non-conforming products are on display at trade fairs (Sec. 26 FuAG), if technical documents contain errors (Sec. 27 FuAG) and in cases of formal non-compliance [i.e. if, for example, the marking with "CE" is missing (Sec. 28 FuAG)].

## PACKAGING REGULATION

In 2019, an extensive instrument has been created for the placing onto the market, recovery and disposal of packaging, in the form of the Packaging Act (VerpackG), which repealed the previous Packaging Regulation of 1992.

**What obligations exist?**

Distributors placing retail or grouped packaging filled with goods that typically accumulates as waste with private final consumers after use onto the German market on a commercial basis (referred to as "producer" in the Packaging Act) are obliged to register packaging with the **Zentrale Stelle Verpackungsregister** (Central Agency Packaging Register – **ZSVR**), and to submit the same data reports provided to the dual systems about the packaging placed onto the German market to the ZSVR. From 1 July 2022 onwards also producers of packaging which not typically accumulates as waste with private final consumers (e.g. Reusable and transport packaging) have to register.

The Packaging Act provides for higher recycling quota, requires a minimum standard for determining the recyclability of retail packaging, expands the influence of municipalities on the structure of how retail packaging is collected locally, and sets out clearer controls for waste management systems.

It also provides for higher requirements on experts, auditors, tax advisers and sworn accountants who undertake auditing activities, and brings into effect new requirements for beverage packaging.

**Who is obliged?**

In this context, the legal situation will change significantly due to the change in law in the coming years. However, as a rule of thumb the following is helpful: The person who puts the sales packaging into circulation for the first time is subject to the obligations of the VerpackG.

A "**producer**" as meant by the Packaging Act is therefore:

- the **initial distributor**, i.e. who fills and places onto the German market for the first time empty packaging that typically accumulates with private final consumers,
- the **importer**, namely who imports packaged goods into Germany that typically accumulate with private final consumers, and places them here onto the market for the first time (as a general rule, the party who bears legal responsibility for the goods at the time they cross the border is the importer), such as

  - any party located abroad that ships the goods to Germany or
  - any party located in Germany that orders the delivery.
- **mail order companies or businesses or online retailers**, i.e. any party in the mail order business sector who fills and places onto the German market for the first time shipment packaging that typically accumulates with private final consumers;
- in the case of **service packaging**, the final distributor thereof can also request, as an exception, that the manufacturer / initial distributor of the empty packaging bears the registration requirement.

Manufacturers is not deemed a "producer" and thus not required to register if they produce packaging and place it onto the German market as **empty packaging**.

Distributors are only allowed to resell "compliant" packaging which comes to the end customer; in the future, this will also apply to fulfillment service providers and operators of online platforms as well as with regard to a broader scope of packaging.

### Consequences of a violation

Non-compliance with the Packaging Act may entail an automatic **distribution ban** on all packaging materials and fines of up to **EUR 200.000**.

## ECODESIGN & ENERGY LABELLING

The ecodesign of products is subject to specific requirements in terms of environmentally compatible. The core of the statutory regulation regarding design requirments is the Ecodesign Directive 2009/125/EC. Besides that, certain products have to be labelled with their energy consumption needs according to the framework Regulation (EU) 2017/1369 ("**ERPR**") and its supplementing delegated regulations.

### What obligations exist?

The Ecodesign Directive applies to **energy consumption relevant** products, i.e. all objects whose use is influenced by the consumption of energy (except for means of transport, see Art. 1 III, Art. 2 No. 1).

The ErPR applies through its supplementing **delegated regulations** on several products, the EU offers a good product based overview.

### Who is obliged?

The **ecodesign** obligations primarily affect the **manufacturer** and, if the manufacturer is outside the EU and has no authorised representative, the **importer**. They also affect those parties which **put** a product **into service**.

**Energy labelling** obligations are allocated throughout **the whole distribution chain**. While the manufacturers e.g. have to draft the standardized energy consumption overviews, distributors have to make sure that these overviews are displayed (on- and offline) when selling the affected products.

On **30 March 2022**, the European Commission published a proposal for a framework regulation on setting ecodesign requirements for sustainable products "Draft Ecodesign Regulation", which aims to revise the existing Ecodesign Directive in order to increase the sustainability of products placed on the EU market in compliance with the objectives set out in the Circular Economy Action Plan.

### Consequences of a violation

The Ecodesign Directive is implemented in Germany by the law on the environmentally sound design ("*EVPG*"). It governs the conditions for bringing energy consumption relevant products onto the market or putting them into operation, market monitoring by the authorities and their measures if products do not adhere to Art. 4 EVPG (i.e. the requirements for ecodesign, the CE marking and the declaration of conformity). If they are not adhered to, authorities can impose **sales bans**, organise the **withdrawal** and **recall** of the product and / or impose **fines**.

## ELECTRICAL AND ELECTRONIC EQUIPMENT ACT

The aim of the Electrical and Electronic Equipment Act ("ElektroG") is to avoid waste and to achieve the highest possible recycling rate for equipment powered by electricity.

### What is affected?

**Electrical and electronic equipment** of certain categories are covered by this law. In 2018, with the implementation of the WEEE Directive (2012/19/EU), the scope of application of the ElektroG was broadened ("open scope"). It now extends to all electrical and electronic equipment that falls into one of the six categories specified by law, so that clothing and furniture with an electronic function, for example, now are also covered by the ElektroG.

**Tools and production facilities** are only covered if they are not used as large-scale fixed installations for industrial production or are operated with electricity of over 1,000 Volts AC or 1,500 Volts DC.

Since 1 May 2019, ElektroG also applies to **passive electrical and electronic equipment**. Passive equipment does not have any own, active functionality and covers antennas, adapters, junctions, power distributions, certain plugs and sockets, ready-to-use cables, certain switches and push-buttons, and fuses.

Since January 2022, the ElektroG changed once more and new obligations are applicable, and certain actors are assigned new roles and obligations. The amendment introduces

- for manufacturers, (a) stricter manufacturing obligations for battery-powered devices, aimed at reducing hazards caused by damaged lithium batteries, (b) the obligation to submit a take-back concept for equipment not meant to be used in private households, (c) the obligation to mark with the symbol of the crossed-out wheeled bin all electrical and electronical equipment, as well as (d) extended information obligations to private households and (e) stricter requirements for taking back the equipment from users other than private households;
- for distributors, (a) extended take-back obligations and (b) new information obligations, especially to end users they directly deliver to;
- for authorized representatives, (a) an authorization to be granted for at least three months and (b) the official approval of the competent foundation (the *Elektro-Altgeräte Register*, EAR) as of 1 January 2023;
- for operators of electronic marketplaces and fulfillment service providers, as of 1 January 2023, new assessment obligations, aimed at

introducing an additional mechanism against the placing on the market of electrical equipment by unregistered producers.

**What obligations exist?**

The current version of the ElektroG already contains a multi-level catalogue of requirements.

**Construction requirements** are intended for waste prevention and the possibility of recycling components for devices already in the planning phase.

A **requirement to register** with the EAR is intended for the economically highly relevant obligation to collect all old equipment from private households at collection points, usually recycling centres, and to recover and dispose of these devices.

A reasonable **option** must be created for **recovering** devices from the commercial sector (**B2B equipment**) outside the recycling centres. Since January 2022 the recovering obligation may no longer be passed on to the user, however, manufacturer and user may agree on a deviating cost allocation (Sec 19 III ElektroG). Manufacturers of B2B equipment must submit a recovery concept for new registrations or – in the case manufacturers already have a registration in place – manufacturers have to submit such concept by 30 June 2022.

The recovery obligation does not mean that the devices will be collected separately in the recycling centres by manufacturer and collected and disposed there when a minimum quantity has been reached. Instead, a manufacturer from the responsible authority will be asked to pick up a collection container that is filled with the class of "its" devices (such as entertainment electronics devices), regardless of whether the container contains its own devices or not.

In order to simplify separate collection, manufacturers must mark electrical and electronic equipment with the symbol of a crossed-out dust bin:

Registered devices must be specially **marked**.

Dealers of equipment with a sales area of at least 400 square metres are obliged to collect electronic equipment free of charge. Also food retailers with a warehouse and shipping area of at least 800 square meters are obliged to take back equipment.

**Consequences of a violation**

If the obligations provided by the ElektroG are not complied with, the device is not marketable and may not be placed on the market. Fines amounting up to EUR 100.000 may also apply and/or warnings may be served by the competition.

## BATTERIES

On 1 January 2021, the latest amendments of the Batteries Act ("**BattG**") entered into force. The aim of the amendment is to transpose into national law Directive 2006/66/EC on batteries and accumulators and their disposal (**Batteries Directive**).

The most important change for manufacturers and distributors who want to bring batteries onto the market in Germany is the introduction of **compulsory registration with the EAR**. This registration replaces the previous obligation to report market participation to the UBA. Moreover, the new Batteries Act introduces **minimum standards for containers** used by the manufacturers' collection schemes for collection and pick up, as well as **extended information obligations**, a **joint information and public relations work obligation** for collection schemes and a **higher collection rate** for waste portable batteries of at least 50 percent. Existing manufacturers' responsibility schemes have to be aligned with the new requirements by January 2023.

The new Batteries Act also **prohibits** the placing on the market

- of batteries containing more than 0.0005 percent of **mercury** by weight, or
- portable batteries containing more than 0.002 percent of **cadmium** by weight.

Portable batteries for emergency or alarm systems including emergency lighting, medical equipment and cordless power tools are exempt from this prohibition.

Subject to the new Batteries Act are those who are bringing batteries onto the market in Germany on a commercial basis for the first time. These are generally **battery manufacturers** and **distributors who are importing** the batteries or sending them to Germany from abroad. Furthermore, **distributors or intermediaries** offering batteries from manufacturers who or whose authorised representatives are not (properly) registered are also considered to be manufacturers within the meaning of the Batteries Act.

A "**game changer**", on the other hand, will be the **Battery Regulation**, which is available in draft form (COM(2020) 798 final). For the first time in product-related environmental law, a life-cycle-based approach will be chosen (with safety requirements, conformity assessment and environmental aspects), which will place uniform obligations on economic actors throughout Europe.

## LABELLING LAWS

Labelling laws have a broad scope of application which ranges from very general requirements (such as general warnings) to very product-group specific requirements (such as those in pharmaceutical law). It is therefore only possible to provide a brief overview below.

**What is affected?**

**General labelling requirements** are mainly used for the manufacture and sale of machinery and dangerous objects, but also for "consumer products", i.e. all products that are intended for use by consumers. ProdSG, in particular, contains guidelines in relation to this with its implementing provisions (see above).

**More specific provisions** on labelling law are mainly contained in the specific regulations

- on hazardous substances (such as the aforementioned CLP regulation),
- on dangerous preparations,
- on energy consumption ("*EU label*") and environmental labels,
- on cosmetic products,
- on animal feed,
- on medicinal products and
- on the fuel consumption of new passenger cars.

**What obligations exist?**

In addition to specific labelling regulations, the main obligation is to attach

the *CE marking* if the product falls under one of the now more than 20 EU Directives that provide for compulsory labelling (see above).

By applying the CE marking, the manufacturer confirms that the product complies with the requirements under EU law. Only then can it be sold in the EU, which is why it is also referred to as a **"product passport"**. The process that must be gone through before attaching this conformity mark is, however, inconsistent. In some cases, the manufacturer can and must assess for themselves whether the guidelines have been met. In others, construction types must be checked by an independent third party. They must even go through an approval procedure sometimes.

**Who is obliged?**

The **manufacturer** is obliged. It can appoint an *authorised representative* to meet its obligation to affix the CE mark. There are also differentiated obligations for importers and traders.

**Consequences of a violation**

Incorrect or incomplete product labelling may be punishable with fines as a breach of the law. Aside from official measures, warnings may be issued by competitors.

Further information on this can be obtained from the EU Commission: http://ec.europa.eu/growth/single-market/ce-marking/index_en.htm

## SPECIAL LABELLING OF FOOD

Special attention must be paid to the correct labelling of **food** and the **design of its packaging**.

**What is affected?**

Food, primarily pre-packaged food that is supplied to consumers is affected.

**What obligations exist?**

There are special legal requirements in numerous EU regulations and German laws (partly general for foodstuffs, partly product-related) relating to

- the labelling, presentation and advertising of foodstuffs,
- the packaging of products (weight and volume) and for the approval of packaging sizes,
- measures for determining the package batch to which a foodstuff belongs,
- frozen foodstuffs,
- particular specialities for agricultural products and foodstuffs,
- the protection of geographical indications and indications of origin,
- agricultural products and foodstuffs from organic cultivation,
- nutritional labelling,
- nutritional value and health-related information,
- coffee and chicory extracts,
- caffeine and quinine,
- foodstuffs that are intended for particular nutritional use,
- foodstuffs for a low-calorie diet to lose weight,
- dietary foods for special medical purposes,
- food supplements and vitamins, as well as
- the treatment of foodstuffs with ionising radiation.

There are further specific obligations for the manufacture and distribution of **beverages**, such as in relation to

- the definition, labelling and presentation of flavoured drinks,
- the labelling of alcoholic beverages,
- the definition, labelling and presentation of spirits,
- the labelling of and correct geographical indications for spirits,
- the labelling of wine and specific wine products,
- mineral water and fruit juices.

There are also special requirements for **food additives** such as

- food enzymes,
- colourings,
- permitted sweeteners and
- aromas.

The information requirements of food companies have largely been standardised in the Food Information Regulation ("FIR") since 13 December 2014. The FIR consistently governs the labelling of foodstuffs (Art. 3 et seq.) and nutritional values (Art. 29 et seq.) in the EU as a whole. In Germany, the FIR is complemented by the national Food Information Implementing Regulation (LMIDV).

**As a general rule**, 12 different pieces of information must be specified for the trade in foodstuffs (Art. 9 FIR). These include food labelling, ingredients (including quantity), any **allergenic substances**, net quantity, best before date or consumption date, information on food business operators, on storage / use / application, on the place of origin or provenance and, if applicable, the alcohol content and nutritional values declaration (the latter from 2016, see Art. 55 FIR). Art. 12, 13 and 15 FIR govern the type and place of the labelling.

Depending on the food, there is, **if necessary, further mandatory information** (such as for food containing sweeteners or added caffeine, Art. 10 FIR) or exceptions (for example, no obligation to provide lists of ingredients on alcoholic beverages, Art. 16 FIR). The mandatory information must be recorded in a "*language which the consumer understands*" (Art. 15 FIR).

For the sale of **food & wine online**, since December 2014 it has been necessary to provide consumers with specific information, in accordance with FIR. Information on ingredients and processing aids in foods that are sold online (prepacked or loose) and which may cause allergies or intolerances must be obtained **before the conclusion of the purchasing agreement** (see Art. 14, 44 and 9 and Annex II FIR). This also applies to sales through other means of telecommunication (e.g. mail order business).

**Who is obliged?**

**Food business operators** are obliged, i.e. the persons responsible for food control in each company that is responsible for the production, processing or sale of food.

**Consequences of a violation?**

Aside from official measures (up to and including withdrawal from circulation), fines and penalties, warnings may be issued by competitors.

## SPECIAL LABELLING OF TEXTILES

The Textile Labelling Regulation (EU/1007/2011) and the implementing German Textile Labelling Act stipulate that details be provided for the fibre composition of textiles. The purpose is

to protect consumer interests and eliminate potential obstacles to the proper functioning of the internal market of textiles and clothing.

**What is affected?**

**Textile products**, i.e. goods that are produced from textile raw materials (especially fibres and hair) that constitute at least 80% of their weight (including upholstery material on furniture). Excluded from this are toys and disposable items (but not wadding).

**What obligations exist?**

Textile products must be provided with **information on their fibre composition**. It is sufficient to provide this information on the packaging when selling to end consumers. The information must include the **percentages of weight of the used fibres** (in % of the net weight), starting with the fibre the products contain the most.

**Who is obliged?**

Companies who provide textile products on the EU market (i.e. offer them for sale, consumption or for use as part of business activities there) are obliged.

### Consequences of a violation

Incorrect or missing information may result in fines. Warnings may be issued by competitors.

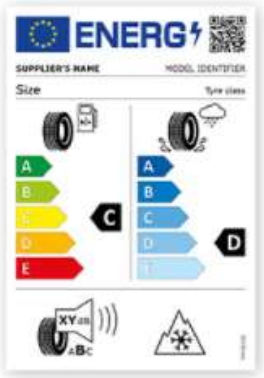
## SPECIAL LABELLING OF TYRES

While the requirements for tyres to be placed on the European market are set forth in the Regulation 661/2009/EC on general safety of motor vehicles (s. next para.), the labelling requirements are defined in a specific regulation and have recently been updated.

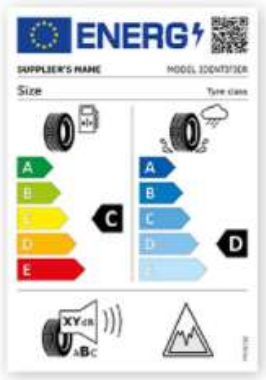
**New labelling rules** are, in fact, applying since **1 May 2021**, as per the new Regulation (EU) 2020/740, replacing the previous Regulation (EC) 1222/2009, which first introduced the obligation of labelling **car and van tyres**. The new rules are extended to cover **bus and truck tyres**, and introduces options to show if the tyres are suitable for use in severe snow conditions or in extreme climatic situations.

Under the new regulation, in addition to information on rolling resistance, breaking on wet surface and external noise, and the classes, the tyre label may display **2 additional parameters**:

- **Winter tyres** approved for use in severe snow conditions carry a specific pictogram, called the **"alpine symbol" or 3PMSF** (3 peaks mountain with snow flake). To have the pictogram the tyre has to pass a specific test for braking on a road with snow. The same pictogram appears on the tyre sidewall.




- **Nordic winter tyres** approved for use in extremely cold conditions also carry a specific pictogram, representing an **ice stalagmite**. To bear the pictogram, the tyre has to pass a specific test for braking on extreme ice. These tyres are only marketed in Nordic countries and should be used in extremely cold winter conditions. Usually, these tyres do not work well on a wet surface or in less severe winter conditions.




Standardised tests are used to assess the performance of tyres in all the 5 parameters indicated on the label. Only tyres reaching a predetermined **minimal performance level** can carry the snow or ice symbol. National authorities perform random controls to check the accuracy of the performance levels.

Vehicle manufacturers also have to provide information on the tyres for that vehicle to customers.

## TOY SAFETY DIRECTIVE

The Toy Safety Directive 2009/48/EG was adapted by a series of later directives (e.g. Directive 2017/738/EU, fixing migration limits for lead) to technical progress. It was transposed into national law in Germany by the second regulation on the Product Safety Act (2. GPSGV).

**What is affected?**

The Toy Safety Directive applies to products designed or intended for use in play by kids under 14 years of age. Within the scope of the Directive fall products that can be defined as toys, except for:

- playground equipment designed for public use,
- automatic playing machines intended for public use,
- toy steam engines,
- toy vehicles armed with combustion engines,
- catapults and slings.

Some products can be defined as toys under the Toy Safety Directive providing they meet specific criteria are; for example, painting articles like chalk, wax crayons etc. are considered toys as long as they are not used for artistic purposes and sold in shops specialised in artists' equipment.

**What obligations exist?**

Obligations under the Toy Safety Directive include product's design and manufacture requirements (e.g. the new lead limits for toys or toy components are 2.0 mg/kg in dry, brittle, dusty or pliable toy materials, 0.5 mg/kg in liquid or adherent toy materials and 23 mg/kg in scraped toy materials), as well as any other obligation applicable to products bearing the CE marking.

**Who is obliged?**

Economic operators subject to the obligations of the Toy Safety Directive are **manufacturers** and their **authorised representatives, importers** and **distributors** of toys.

### Consequences of a violation

Non-compliance with the Toy Safety Directive may entail sanctions under criminal law (as per Sec. 22 2. GPSGV in connection with Sec. 40 ProdSG), including imprisonment.

## PPE REGULATION

The Regulation 2016/425/EU lays down requirements for the design and manufacture of personal protective equipment ("**PPE**").

**What is affected?**

The PPE Regulation applies to the PPE described in Art. 3 no. 1 (with the exception of those described in Art. 2.2), e.g. equipment designed and manufactured for personal protection against any risks for the person's health or safety, its interchangeable components and connection systems. These products may be made available on the market only if, when properly maintained and used for their intended purpose, they comply with the same Regulation and do not endanger the health or safety of persons, domestic animals or property.

**What obligations exist?**

The economic operators concerned will have to take into account a number of amended criteria and obligations, the presence of which will lead to the issuing of the conformity assessment.

**Who is obliged?**

The PPE Regulation is addressed to **manufacturers, authorised representatives, importers and distributors**.

**Consequences of a violation**

Pursuant to Art. 45 of the PPE Regulation, Member States shall lay down rules on penalties for economic operators, which may include criminal sanctions for serious infringements. The penalties provided for shall be effective, proportionate and dissuasive and may be increased if the non-compliant economic operator has previously committed a similar infringement of the PPE Regulation.

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## IF YOU HAVE ANY QUESTIONS, PLEASE DO NOT HESITATE TO CONTACT US!

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