Product Recall 2022

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Getting The Deal Through

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Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

Lexology Getting The Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to the contributing editor, Sarah-Jane Dobson of Kennedys Law LLP, for her assistance with this volume.

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Germany

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PRODUCT SAFETY LAWS

Product safety legislation

1 | What basic laws govern the safety standards that products must meet in your jurisdiction?

In Germany, the general requirements for making a product available on the market are set out in the German Product Safety Act (ProdSG), which implements Directive 2001/95/EEC on general product safety (GPSD). In this respect, especially the stricter requirements in section 6 ProdSG for consumer products (ie, information and labelling obligations) must be taken into account.

In addition, depending on the product to be placed on the market, many other requirements may apply in individual cases to ensure safety and health. This is true, for example, for the area of electrical equipment, simple pressure vessels or pressure equipment, machines and toys. In these cases, the ProdSG can at least be applied in a supplementary manner. In contrast, the ProdSG does not apply at all to products such as medical devices, food and feed, plant protection products, live plants and animals, antiques, used refurbished or reconditioned products, for which special legal regulations exist.

Basic pre-launch requirements

2 | What basic steps and safety requirements must be satisfied before a product can be marketed in your jurisdiction?

Before a product is placed on the market, possible risks of a product must be assessed. This also includes parts of a product manufactured by third parties. All stages of the product cycle must be considered, such as transport, installation, operation, maintenance, cleaning, troubleshooting and repair. Alongside the intended use, the foreseeable use of a product should always be taken into account, as the product must be safe for both. Changes to the product must be rechecked for safety. Defects in the product must be rectified immediately.

Eventually, a complete documentation is required, which includes the following: Instructions for use and operation, safety instructions, description of the product, technical data, name and address of the manufacturer, service addresses and suppliers of accessories and spare parts, installation instructions, guarantee or warranty information as well as information on decommissioning, cleaning and disposal. The EU declaration of conformity must be issued, the CE marking – if necessary – must be permanently affixed to the product and a clear identification marking must be affixed to the product (eg, type, batch and serial number).

Guidance

3 | Is there any guidance on the application of the product safety legal framework, or related commentary around its effectiveness?

Guidance on the application of the product safety legal framework can be found in the 'Product Safety in Europe' guide of the European Commission dated June 2004.

ENFORCEMENT OF PRODUCT SAFETY LAWS

Regulators

4 | Who enforces the product safety laws in your jurisdiction? If there are multiple regulators, how do their activities intersect and to what extent do they cooperate?

Pursuant to section 24(1) ProdSG, market surveillance is in principle a matter with the 16 German federal states. In this respect, each federal state appoints a market surveillance authority and provide it with sufficient qualified personnel. The responsibilities for enforcement diverge depending on the internal organisation of the individual federal state. In most federal states, the market surveillance authority or state office is responsible, in some cases the regional council. The local competent authority is the one in whose district the relevant manufacturer, importer or distributor (economic operator) has its place of business.

In addition, the 16 German federal states, in cooperation with the federal government, have organised the Working Committee on Market Surveillance (AAMÜ) to ensure uniform administrative practice in the enforcement of the ProdSG and to avoid duplication of work. For certain products (eg, medicinal products, automobiles) and tasks (eg, customs authorities for imported goods), also other authorities, some of which are integrated into the German Federal Republic administration, enforce the product safety regulations.

With regard to cooperation between customs and market surveillance authorities, for example, section 24(2) ProdSG stipulates that the customs authorities are entitled and obliged to pass on all information required for further measures to the competent market surveillance authority. This includes, in particular, the registration number and date of the customs declaration, name and address of the consignor, name and address of the consignee, country of consignment, country of origin, description and type of goods, quantity of the declared goods and code number. This enables the market surveillance authorities to intervene at the earliest possible stage and to obtain information on products from third countries.

Enforcement actions and penalties

5 | What enforcement actions are available to the regulatory authorities? What penalties may they impose for non-compliance with product safety laws?

Pursuant to section 26(2) ProdSG the authorities have power to ban marketing of unsafe products (prohibition of placing on the market, prohibition of further distribution, obligation to make improvements) and order a recall. In addition, the authorities are entitled to seize a product, destroy it or otherwise render it unusable.

In the case of qualified violations of product safety, the market surveillance authority can impose fines of up to €100,000 (section 39 ProdSG) or, in the case of repeated and persistent violations, involve the public prosecutor's office to investigate possible criminal offences (section 40 ProdSG). Criminal prosecution can affect managing directors and board members, but also subordinate employees.

It should only be mentioned that violations of relevant provisions of the ProdSG can trigger consequences under unfair trade practices law such as warning letters, cease-and-desist claims and compensation payments.

Enforcement process and procedures

6 | What is the typical process for enforcement actions and what procedures are involved? What rules govern enforcement actions?

If a safety-related issue occurs, the authority will typically coordinate with the economic operator to pursue the appropriate remedies. In the event of a refusal to cooperate, the market surveillance authority may order the remedies itself.

Lacking a separate stipulation in the ProdSG, the administrative enforcement of orders pursuant to section 26(2) ProdSG is governed by the enforcement provisions of the respective federal state. If, on the other hand, the ProdSG is enforced by a federal agency, such as the Federal Motor Transport Authority (KBA), the German Federal Administrative Enforcement Act (VwVG) applies.

Enforcement trends

7 | How prevalent is enforcement action under the product safety laws? Have there been any notable recent examples of enforcement actions?

Not particularly relevant, as cooperative behaviour is the rule. To illustrate, the state can require a company to engage in a jointly coordinated recall, but cannot carry out the recall itself. If, to all appearances, a recall is organised by an authority in Germany, it is at best the enforcement of a recall order in the (rare) case that the company has refused any cooperation. For reasons of its own market reputation, hardly any company dares to take such a blocking stance.

Challenging enforcement actions

8 | What mechanisms are available to companies to challenge the imposition of enforcement actions?

A distinction must be made between legal protection available against the order of the market surveillance authority, which is primarily to be challenged, and legal protection against the enforcement measure. The central norm for legal protection in administrative enforcement proceedings is section 18 VwVG. Pursuant to this, the legal remedies admissible against the administrative act to be enforced are available against the announcement or application of enforcement actions. To this extent, however, a limited standard of review applies, since only the effectiveness, but not the lawfulness of preceding administrative actions is a prerequisite for the lawfulness of subsequent enforcement actions.

NOTIFICATION REQUIREMENTS

Criteria for notification

9 | What events or conditions trigger a requirement to notify the product safety authorities of issues discovered in products, or known incidents of personal injury or property damage?

Economic operators have notification obligations towards the market surveillance authorities pursuant to section 6(4) ProdSG. As soon as they know or should know on the basis of experience or information that their product poses a risk to the safety and health of persons (not property), they must inform the market surveillance authority. Since the relevant criterion is the risk, notification may be required even if no incident has yet occurred. In this respect, it depends solely on the quality of the risk, which must have a certain significance. But even in low-risk constellations, it is advisable to proactively approach the competent authority and bring a risk assessment to its attention, as this reduces the risk of a fine.

Notification time limits

10 | What are the time limits for notification?

The notification must be made immediately. Whereas according to German legal understanding, immediately means 'without culpable delay', the guidelines issued by the European Commission define the term in three stages depending on the intensity of the hazard:

- within 10 days of the existence of reportable information on the existence of a dangerous product, even if investigations are still ongoing;
- within three days if there is a 'serious risk'; or
- as soon as possible if a company initiates 'emergency measures'.

Competent authority for notification

11 | To which authority should notification be sent? Does this vary according to the product in question?

The notification is to be sent to the competent market surveillance authority, which in the vast majority of cases is determined by federal state law and is located at the place of business of the obligated economic operator. Depending on the type of product, a different authority may be responsible, for example the Federal Network Agency (BNetzA) in the case of a risk emanating from the electromagnetic incompatibility of the product, or the KBA in the case of motor vehicle risks.

Form and content of notification

12 | What form should notification take? What product information and other data should be provided in the notification to the competent authority?

There is no specific form for the notification of authorities. The notification can therefore – especially in urgent cases – also be made electronically. If desired, the Product Safety Business Alert Gateway provided by the European Commission can be used as a reporting and notification template.

The notification must include:

- information identifying the product;
- a comprehensive description of the risks posed by the product;
- any available information which contributes to the traceability of the product; and
- measures already taken to prevent risks to consumers.

Obligations to provide updates after initial notification

13 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries following an initial notification?

Beyond the aforementioned obligation within the scope of notification to inform the authority about measures already taken to prevent risks to consumers, there is no further obligation for the relevant economic operators. In particular, economic operators do not have to provide information on the individual implementation steps of such measures on a piecemeal basis. The situation is different only in cases of administrative recall orders. The authority may in this case include an order to provide progress reports. If only in the economic operator's own interest, it is advisable to meet the authority's expectations for regular progress reports or at least a report on the completion of the recall.

Penalties for failure to notify

14 What are the penalties for failure to comply with notification obligations?

Failure to inform the authorities, or failure to inform them correctly, completely or in good time, can be punished as an administrative offence with a fine of up to €10,000.

Public disclosure of notification information

15 Is the content of the notification publicly disclosed by the authorities? Is commercially sensitive information contained in the notification protected from public disclosure, or are the authorities otherwise bound by confidentiality?

The content of an authority notification is in principle confidential and therefore not published. Even if a private person requests information from the authority on product risks, violations of product safety law or monitoring measures by the authorities pursuant to the Consumer Information Act (VIG), the authority may not disclose the information provided in the context of an authority notification pursuant to section 6(4) ProdSG automatically. However, this privilege does not extend to information that the authority obtains on the basis of its own investigations initiated by the notification.

Use of information in prosecution

16 May information notified to the authorities be used in a criminal prosecution?

Pursuant to section 6(4)(3) ProdSG, the notification may not be used for criminal prosecution or for proceedings under the law on administrative offenses (prohibition of exploitation). Nevertheless, the notification can initiate administrative proceedings in the course of which facts are uncovered that are not themselves subject to the prohibition of exploitation under section 6(4)(3) ProdSG. The 'self-disclosure' of the economic operator thus does not have the effect of exempting him or her from punishment, but may ultimately result in a sanction under administrative offences law or even a criminal prosecution (eg, for negligent bodily injury or homicide).

Information sharing between regulators

17 Is notification information shared with other regulators?

The information submitted in the context of the notification does not remain with the market surveillance authority, but is passed on nationally and in Europe. In this respect, a notification automatically triggers further notifications from the competent authorities to the Federal Institute for Occupational Safety and Health (BAuA) and to the other European market surveillance authorities. The latter take place via the ICSMS system or – in cases of 'serious risk' – via the Rapid Exchange of Information System (RAPEX). In this way, authorities in the EU member states can react quickly and take the necessary measures.

CORRECTIVE ACTIONS AND RECALLS

Criteria for corrective action

18 What criteria are applied to determine when a matter requires a product recall or other corrective action?

Under the wording of section 26(2) ProdSG, the mere suspicion of a product's non-conformity with applicable product safety law is sufficient for the authorities to take action. Accordingly, the competent authority examines whether there are sufficiently solid suspicions that a product does not comply with the legal requirements. Examples of the existence of solid suspicion within the meaning of section 26(2) ProdSG are the following cases:

- the defect in the product is obvious;
- the declaration of conformity is not submitted upon request;
- the result of a laboratory test within the meaning of section 26(1) ProdSG reveals a defect; or
- technical documentation on the product is not submitted upon justified request of the market surveillance authority, although this documentation must be available.

Scope of corrective action

19 What criteria are applied to determine the scope of a corrective action?

The legislator of the ProdSG did not grant the market surveillance authorities any discretionary power, namely, no authority to decide whether measures should be taken if there is a suspicion of danger. Rather, such measures are then mandatory.

In contrast, the market surveillance authorities have a discretionary power with regard to the type and manner of intervention. This relates both to the concrete measure (eg, definitive prohibition of provision or recall) as well as to the addressee of the measure (cf section 27 paragraph 1 ProdSG). Nevertheless, there are limits to the exercise of discretion at this point. In principle, the market surveillance authorities must be guided by the best possible protection of the integrity of the product user or third parties when selecting the measure. Factors that must necessarily be identified by the acting market surveillance authority include, for example:

- the severity of the threatened injuries or the intensity of the threatened impairment of protected legal interests;
- the likelihood of the occurrence of damage and thus also the type, scope and frequency of the dangerous product use;
- the circle of users or consumers;
- the degree of distribution of the product in question;
- the content of instructions for use; and
- any possibilities of the user to protect him or herself.

Traceability requirements

20 What requirements exist for the traceability of products to facilitate recalls?

Manufacturers shall affix clear product identification markings for the purpose of traceability. For consumer products, this clearly results from section 6(1)(1)(3) ProdSG. In the area of B2B products, there is no requirement under product safety law for product labelling. However, in view of the mere existence of the recall as an original market surveillance measure, economic operators are well advised to make the

products they manufacture or make available on the market traceable. Moreover, the recently reformed ordinances on the ProdSG, the German Electromagnetic Compatibility Act (EMVG) and the German Radio Equipment Act (FuAG) provide for specific requirements on identification labelling.

Consumer messaging

21 | What are the legal requirements to publish consumer notices, warnings or other information to product users or to suppliers regarding product issues and associated hazards, or to notify consumers of recalls?

The warning as a standard measure within the meaning of section 26(2) ProdSG requires that the product users and uninvolved third parties are confronted with product risks. The term 'risk' must be interpreted restrictively against the background of the principle of proportionality. Specifically, this means that the product risks must relate to the legal interests of life, body and health of the end users or third parties. The protection of material assets, on the other hand, will only be sufficient to justify a warning under constitutional law in exceptional cases. In any case, the warning presupposes positive knowledge or certainty about the hazard of the product. In contrast, a well-founded suspicion of product risks is insufficient.

Content of recall notices

22 | Are there any requirements or guidelines for the content of corrective action or recall notices?

Pursuant to section 2(25) ProdSG, a recall is understood to be any measure 'aimed at obtaining the return of a product made available to the end user.' The KBA has further clarified this definition and understands a recall to be a measure taken by a responsible economic operator that 'aims to obtain the definitive or temporary return by the user of a product that has already been placed on the market. This refers to all actions taken to avert, eliminate or reduce risks posed by such products.' For consumer products, the authorities are even stricter in their handling than for products in the B2B sector.

Mode of communication

23 | What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

In principle, two types of product recall are possible: (1) A silent recall in regard to the distribution stage upstream of the end consumer (recall in regard to the retailer) can be considered if a hazard is possible but not probable. In practice, the authorised dealers are written to and requested to replace the defective products as part of an inspection at the manufacturer's expense. (2) An open recall (recall in regard to the end consumer) can be considered if there are significant product risks and these can only be effectively eliminated by (supplementary) involvement of the media. An open recall is even mandatory if the life or health of individuals or the general public is at danger. For an open recall, typically high-profile media such as radio and television, the print media or the internet are used in order to reach as many users as possible and thus effectively eliminate the product risks.

Time frame

24 | Do any laws, regulations or guidelines specify targets or a period after which a recall is deemed to be completed?

This question can only be answered on the individual case. In the automotive sector, for example, a recall order by the KBA (and the associated monitoring by the KBA) must usually be completed within a maximum period of 18 months. But even then, further measures are possible.

Consumer remedies

25 | What remedies must be offered to consumers affected by a product corrective action or recall? Are there any requirements for how these remedies are offered to consumers?

Notwithstanding any recommendations on recall management, in practice there is no standard recall and only a few standardised recall components. For this reason, an individual and product-related recall action is required.

Because the product safety recall aims at the return of the dangerous product, measures such as retrofitting and refitting, repairs, conversions and replacements are not subject to the recall. Regulations on the rights to rectification, subsequent delivery and reduction are reserved for civil law, especially as any limitation rules are also laid down there.

Returned products

26 | Are there any requirements for proof of disposal of returned products subject to recall or corrective action? Are there any reasons why such products should be retained by the manufacturer responsible?

Pursuant to section 26(2)(2)(8) ProdSG, the market surveillance authorities can seize dangerous products and – if the identified product hazards cannot be prevented by other means – order that they be rendered unusable. There are three variants of rendering a product unusable: destroying it, having it destroyed or rendering it unusable in some other way. The rendering unusable is not subject to compensation. The addressee must comply with the order. Apart from such cases of compulsory ordered rendering unusable, it may be useful to retain products for preservation or as evidence.

Penalties for failure to recall a product

27 | What are the penalties for failure to undertake a recall or other corrective actions?

Anyone who fails to properly carry put an ordered warning to the public about product risks is acting in breach of the regulations and can be punished with a fine of up to €100,000, sections 39(1)(8)(b) and 39(2) ProdSG. The same applies with regard to a recall order, provided that it has been declared immediately enforceable.

In the case of an intentional act that is persistently repeated or that endangers the life or health of another person or property of significant value, even prosecution as a criminal offence is possible, section 40 ProdSG.

AUTHORITIES' RECALL AND CORRECTIVE POWERS

Corrective actions

28 | What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

If the addressee does not comply with a recall order, the market surveillance authority will finally react to this – after exhausting all means of cooperation – with the means of administrative enforcement law. The authority can first increase the pressure on the economic operator to recall by threatening and imposing a penalty payment, or finally organise the recall itself by way of substitute performance. The

substitute performance is usually less suitable in practice because the delivery, storage and safekeeping of the recalled (dangerous) products is likely to cause considerable difficulties without the constructive cooperation and logistical support of the economic operator concerned.

Government recalls

29 | Can the government authorities organise a mandatory product recall where a producer or other responsible party has not already done so?

Yes, they can.

Voluntary versus mandatory recalls

30 | Are product recalls generally undertaken voluntarily or mandatorily in your jurisdiction?

Product recalls are usually mandatory, at least as far as there is a risk of serious personal injury.

Publication of warnings, corrective actions and recalls

31 | Can the government authorities publish warnings or other information to users or suppliers?

If the economic operator concerned does not warn the public on its own responsibility or not in time, the market surveillance authority itself can warn the public of the product risks in question. The sovereign warning is to be used as ultima ratio in view of its potentially devastating effects in public perception.

In addition to formal warnings, the authority can also issue mere recommendations in connection with the safety of a product, at least in the form of a general recommendation. This serves to inform the public and is regularly addressed to the group of consumers. General recommendations do not identify specific products, product groups, manufacturers or behaviour, and thus do not develop an imperative character. In contrast, a concrete recommendation by the authority that distinguishes certain products, product groups, manufacturers or modes of behaviour as a source of danger for the consumer public is inadmissible because otherwise the special legal requirements of a warning would be circumvented. All aspects mentioned are subject to judicial review.

Costs

32 | Are any costs incurred by the government authorities in relation to product safety issues or product recalls recoverable from the producer or other responsible parties?

If the competent authority chooses a substitute performance with regard to the ordered but omitted measure (in particular recall), it reclaims the costs incurred from the economic operator with a separate cost order. If the substitute performance is formally and materially lawful, the cost order will usually be lawful as well.

Challenging decisions

33 | How may decisions of the authorities in respect of corrective actions or product recalls be challenged?

The prohibition orders, namely the exhibition prohibition, the provision prohibitions, the order of recall as well as the order of warning are administrative actions. The action to be brought is therefore the action for annulment pursuant to section 42(1) of the German Code of Administrative Court Procedure (VwGO). If immediate enforceability has been ordered under section 80(2) VwGO, provisional legal protection must be sought under section 80(5) VwGO. The public warning is a real act. Insofar as legal protection is de facto possible because the economic operator concerned becomes aware of it in time, only a preventive action for an injunction can be considered, which should be accompanied by an application for an interim injunction against the warning.

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IMPLICATIONS FOR PRODUCT LIABILITY CLAIMS

Repercussions for liability in court proceedings

34 | Are the civil courts in your jurisdiction likely to view a corrective action, recall or consumer warning as an admission of liability for defective products?

From a civil law perspective, the implementation of a recall is often seen as 'alleged evidence of the product's defectiveness' in the assertion of contractual claims in general and purchase contract warranty claims in particular (cf Lach/Polly, *Product Compliance*, 3rd edition, page 44). In fact, economic operators' recalls represent reactions to safety defects and thus 'safety recalls', which are to be distinguished from legally not required market correction measures with regard to products with quality defects (cf Schucht in: Klindt, *Produktsicherheitsgesetz*, 3rd edition, section 26 ProdSG, margin 172).

Disclosure of information

35 | Can communications, internal reports, investigations into product issues or planned corrective actions be disclosed in product liability actions? Are there mechanisms to compel regulators to publish information regarding their handling of a corrective action, recall or notification?

In Germany, there is no comprehensive discovery process. In civil proceedings, each party is therefore responsible for gathering and presenting the facts that are favourable to him or her. As long as documents do not need to be kept secret, they may be introduced into the civil proceedings. Possibly unknown or unavailable documents can be requested via information claims against public authorities, since, for example, under the German Federal Freedom of Information Act (IFG) following the 2012 amendment, the information that can be obtained now explicitly extends to consumer products as defined in the ProdSG.

UPDATE AND TRENDS

Key developments of the past year

36 Are there any emerging trends or hot topics in product recall and associated litigation in your jurisdiction?

Official recall orders in the area of general product safety law have been the subject of administrative court rulings on several occasions. Two central points that are always at issue are the determinateness and the proportionality of the measures ordered. On the part of the authority, this requires a professional, effective, mostly cross-border and at the same time financially viable implementation of a product recall as well as legal, technical, sales and communication expertise. From the perspective of those affected, it is often worth taking a closer look in this regard.

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