Product Recall

Contributing editors
Jason Harmon, Alison Newstead and Devin Ross

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GETTING THE DEAL THROUGH

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Germany

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General product obligations

1 What are the basic laws governing the safety requirements that products must meet?

German law does not recognise a basic codification regulating general product safety requirements for each and every product. In lieu thereof, the German Federal Court of Justice has ruled as a general principle – which is based on German Civil Code tort law – that a product must meet the safety standard that the affected business area (consumers or specific entrepreneurs) deems as necessary for such products. The user (and bystander) shall be protected from dangers arising from a product that is used in a regular manner, but also from dangers that arise from predictable misuse. The court thus has developed a legal framework based on general German tort law that may oblige manufacturers to conduct a recall or, as a less severe means, utter a warning.

There exist several specific regulations for specific products (machines, pharmaceuticals, medical products, cosmetics, toys, foodstuffs, etc). Among these are EU directives that must be transposed into national law before they apply as well as EU regulations and national statutes. In contrast to EU directives, EU regulations are classified as a primary source of law, which means they apply directly and have to be interpreted the same way in all member states of the EU. EU directives, however, may be transposed into national law in different ways in different member states, thus leading to a different level of protection from product risks.

The EU General Product Safety Directive (2001/95/EC), which came into force on 15 January 2002 composes a central set of standards of product safety. It was transposed into German law through the Product Safety Act (ProdSG), which has been in force since 1 April 2004 under a different name, the Equipment and Product Safety Act. Its last recast (which merely adapted terms and definitions) came into force on 8 September 2015. The revised version transposes 13 EU directives and one decision into national law to prevent inconsistencies between national law and EU law.

The German Product Liability Act, which has been in force since 15 December 1989, is less important for recall situations, as it primarily addresses a manufacturer's or importer's duty to compensate harm suffered from product risks.

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

German law does not recognise duties regarding traceability of products in general. Just products carrying a very high degree of risk for society such as pharmaceuticals and medical devices are subject to detailed regulation on their traceability. Cars can usually be traced back to the current owner owing to the detailed legal requirements of car registry. Apart from that, it is common in certain industries (such as the automotive industry) to contractually require suppliers to secure traceability of their products. Besides, manufacturers may have an own interest in securing traceability of their products as it may affect their recall costs insurance coverage.

Besides traceability issues, several regulations deal with the labelling of products. With regard to consumer products, the ProdSG contains a detailed comprehensive body of legislation that aims to enable the consumer to identify the manufacturer. To enable traceability, the product or its package must report the producer's name and address or, insofar as it is not based in the European Economic Area, the name and address of the EU representative or the importer. Moreover, unambiguous product identification information must be provided on the product or package.

3 What penalties may be imposed for non-compliance with these laws?

If a product is found to be unsafe, different fields of law may be touched.

Administrative penalties – due to constitutional requirements – are statutorily regulated and their extent depends on the product in question: for example, even minor breaches of duties such as incorrect labelling that prevents traceability of pharmaceuticals may result in penalties of up to €25,000. Other statutes, such as the German cosmetics regulation, refer to the German Food and Feed Code and its penalty system of up to €100,000. Besides financial penalties, the authorities are entitled also to withdraw permission to do business in severe cases.

The most prominent regulation on administrative penalties undoubtedly is the ProdSG. It includes a range of monetary fines from €1,000 to a maximum of €100,000. The system that provides for a certain range of penalties is very much similar to the regulation in other pieces of legislation as it allows authorities to consider peculiarities of a case. Basically, a fine can be imposed for every single illegal conduct in the context of the applicable legislation. The exact amount of the fine, however, is at the discretion of the competent authority and litigable in courts. Whether a fine is adequate or not mainly depends on the quality and severity of the offender's breach of duty the grade of its culpability as well as special circumstances (eg, repeated offence).

Compared to other, especially common law jurisdictions, German law merely provides for limited claims of injured persons. The injured person will have a claim for compensation of the damages caused by an unsafe product. Such damages include material (eg, loss of profit) and immaterial (eg, damages for pain and suffering) aspects. However, German law does not recognise punitive damages. Any breach of duty regarding traceability is unlikely to have an effect on the damages amount. Under special circumstances competitors might have a claim under the regulations of fair trade.

The most severe penalties for a company's board arise from criminal law. While board members generally may be imprisoned if an unsafe product leads to bodily harm or death of third persons, such sanction is imposed quite seldom. It can only be imposed if board members or executive employees acted at least negligently in manufacturing, marketing or not recalling an unsafe product. In most cases, the prosecutions' accusations will confine to negligent conduct and result in a fine. However, if board members or executive employees acted voluntarily in producing unsafe products and human beings were harmed, as, for example, in the matter of defective silicone breast implants or in marketing food such as in the EHEC disease crisis, a term of imprisonment for up to 15 years may be imposed. The exact penalty depends on the details of the case and the impact the product risks had on third persons. In principle, such penalties can also be imposed in connection to breaches of traceability duties and violation of recall duties, for example, if a manufacturer knew about life dangers arising from its products and nevertheless did not conduct a recall.

Reporting requirements for defective products

4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

There is no general provision that requires informing government authorities in case a defect is discovered in products, but special regulations, inter alia for medical devices, pharmaceuticals and foodstuffs, may oblige the manufacturer or importer to immediately inform authorities of a (potential) defect.

The ProdSG (as the main piece of legislation to provide for administrative action) is, inter alia, applicable to, consumer products and provides special duties for the manufacturer, importer and retailer. The manufacturer for example has to examine and collect consumer complaints and notify the competent authorities immediately when it fears a risk to health or safety of consumers. This notification must be issued immediately and without any delay. This obligation will not only come into effect when the producer, representative or importer is positively aware of a defect in a product, but also at the point in time when it knew – or should have known, according to the present information or his or her experience – that the product posed a risk to health and safety. Furthermore, the notification has to include a list of the actions that have already been taken to avoid this risk and will be taken in the future. In order to encourage the obliged parties to notify the authorities the notification may not be used as a basis for administrative fines or for penal prosecution.

Notifying the authorities does not terminate the manufacturer's duty to conduct a recall for which it is solely responsible. The notification shall only enable authorities to examine whether the risk is being controlled appropriately or whether there is a need for further administrative action. Although the authorities might be entitled to conduct a recall of an unsafe product by their own means, it is unlikely they will do so as long as the manufacturer is taking sufficient steps to control the risk.

5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

The criteria for determining whether a notification is necessary vary depending on the category of the product. The higher the risk to human beings, the more demanding the requirements to notify government authorities are. If, inter alia, pharmaceuticals or medical products or possibly lethal products are concerned, the knowledge of a (possible) product defect will likely lead to a notification duty under the ProdSG. In general and for most products a notification will require a product defect and a risk to health and safety of human beings.

The German Federal Court of Justice has developed a tort law duty that a manufacturer is obliged to monitor the market and examine customer complaints in order to assess whether there exists a product defect. The intensity of such monitoring measures depends on the category of the product and its possible impact. If a manufacturer has reasonable and reliable knowledge that some product defect causes a hazard to health and safety of human beings, the authorities will most likely have to be notified. If just minor risks result from the product, the manufacturer may decide not to notify the authorities. Either way, the manufacturer alone carries the risk of a misjudgment, thus is well advised to seek legal and technical advice.

If a manufacturer decides to notify the authorities, this notification has to be carried out expeditiously.

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

Although the ProdSG mentions the term 'market surveillance agency', such an agency does not exist; rather the term abstractly describes an administrative body that carries out the tasks imposed onto the 'market surveillance agency'. A German federal notification authority does not exist.

It is only in special areas, such as medical devices or pharmaceuticals where there are special federal agencies that must be notified such as the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM).

When products are concerned where no special federal agency is appointed as the market surveillance agency, the notification will have to be sent to the competent authority in the state where the defective product is located. Thus the notification procedure depends on the particular state that is affected. For example, in the state of North Rhine-Westphalia the district council is the responsible authority. The state of Hamburg imposed the administrative duties pursuant to the ProdSG onto the department for consumer protection.

Alternatively, notifications can be sent to the Federal Agency of Labour Protection and Labour Medicine, which is the agency that must inform the other state authorities as well as RAPEX (notification procedure to notify the European Commission of product risks).

7 What product information and other data should be provided in the notification to the competent authority?

The information the manufacturer must include in the notification is only regulated in special fields of law. The information is listed in online data sheets that the manufacturer has to fill in.

In general, there is no legislation stating exactly what product information has to be sent to the authorities. If the competent authority does not provide an online notification system, the manufacturer should consider providing information on the following topics:

- brand;
- information as to which product class the product belongs;
- product name;
- model description;
- EAN codes (European article number);
- product description;
- production period;
- customers and customer addresses (if known);
- distribution channels;
- description of the hazard and circumstances when it may occur;
- description of the risks to health and safety as well as probability of occurrence;
- description of already known harms and accidents;
- text of recall or warning (if sufficient);
- information channels used in order to inform customers (especially if consumers); and
- recall measures that have already been taken.

8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

Stipulations defining communication after notification exist in special pieces of legislation (eg, for medical devices or pharmaceuticals). In general, the authorities will include a requirement to be kept updated once the recall has been finalised, or at least be informed in a certain time frame.

9 What are the penalties for failure to comply with reporting obligations?

The authorities may fine the manufacturer. The amount depends on the applicable piece of legislation. The fines are rather low and range from €10,000 to €25,000. If the manufacturer does not comply with reporting obligations, authorities might come to the conclusion that the manufacturer is a continuing danger to the market. Further steps (even closing the business) can be taken by authorities.

Additional penalties, such as imprisonment or (personal) fines for board members under criminal law, are possible. The maximum sentence is imprisonment of one to five years. These further consequences under criminal law as well as damages under civil law require causal personal injury to human beings that could have been prevented had the manufacturer appropriately notified the authorities.

10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

The authorities are bound by law to protect public safety. Generally, the authorities will neither need to obtain nor to share commercially sensitive information with the public. If such conduct indeed should become necessary to protect third parties from imminent or severe danger, authorities certainly are entitled to do so but they have to thoroughly evaluate and assess the impact on the manufacturer. If the authorities did not act adequately, the manufacturer is – to some extent – entitled to compensation.

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

Despite a particular regulation in the ProdSG that the notification may not be used in criminal prosecutions, this regulation explicitly only includes the notification and not additional correspondence. Thus, authorities are not allowed to pass the notification to prosecutors.

However, it is mandatory for the prosecution to investigate potential breaches of duty that might endanger public safety. When authorities order a recall officially, the prosecution could investigate the case. If it does, it is likely that it will use all investigation means legally allowed, and that includes searching and seizure.

Product recall requirements

12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

Product recalls and the requirements for a successful recall are not statutorily regulated in Germany and very little case law exists on product recalls. In the past, the courts mainly had to assess whether recourse claims of the manufacturer against the supplier of the defective product or product part causing the recall were indeed founded. The German Federal Court of Justice ruled in 2008 that a recall has to be conducted when a mere warning is not sufficient to appropriately control the risk. If it is to be assumed that a consumer will not appropriately act on a mere warning, a (free of charge) recall of defective products might be necessary, irrespective of the existence of contractual warranty claims. Such severe measure, however, will merely have to be taken if a certain risk to the health or safety of the user or bystanders exists.

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

A distinction must be made between warnings and recalls by authorities on the one hand and private entities on the other hand.

The requirements for warnings and recalls invoked by the authorities are to be found in the ProdSG and other special regulations. The authorities will have to take appropriate measures if they have reason to suspect that a product is defective and dangerous but have to cease such measures once the manufacturer will have proven that the necessary steps to eliminate the product risks in question have been taken or that the risk assessment was wrong and the true risk level does not justify the measures taken.

Special areas such as medical devices or pharmaceutical liability recognise special regulations regarding the exact time to publish warnings and when to conduct a recall. Generally, a recall will be necessary when there is a danger to human beings and a warning will not be sufficient to eliminate such danger.

14 Are there requirements or guidelines for the content of recall notices?

Statutory regulations covering the content of recall notices do not exist, although guidelines for special products such as medical devices do exist. Generally, it is up to the manufacturer's discretion what actions it will undertake and which content the recall information contains. The recall notice must be coherent. It is to be issued in a way that – depending on the group of customers – enables the average customer to understand the content and importance of the recall notice. Moreover, the notice itself must inform about the danger of the product on the one hand and about the circumstances of its return on the other.

If a manufacturer decides to use retrofitting or upgrades in order to eliminate a product defect, it has to make sure that the instructions for such retrofitting or upgrade are absolutely clear (eg, by use of pictures and descriptions). As a general rule, the more complicated the installation of a retrofitting or upgrade is, the less suitable it is for an installation by the customer him or herself; the manufacturer will bear all risks arising from a wrong installation.

In any case the manufacturer has to minimise the risk and must try to inform any potentially concerned person of the recall.

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

With the exception of special areas of law, there exist no statutory requirements that regulate the exact means of media to be used in a recall scenario. Since the manufacturer has to take adequate and effective steps to minimise the risk to public safety, it has to evaluate the probability and severity of harm to human beings. If courts evaluate the media use to not have been sufficient, the manufacturer's board might face criminal charges as well as claims for indemnification.

Thus it seems safest to make extensive use of different kinds of media such as the internet (manufacturer's own web presence, YouTube and social media channels such as Facebook, Instagram, Twitter, etc), TV and radio while at the same time limiting damage to the company's public image. The use of media, however, strongly depends on the relevant customer group (eg, parents, elderly people, certain professions or online recreational activities).

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

In fact there is no law, regulation or guideline that specifies a satisfactory recall rate. The authorities will order the manufacturer to forward information on the status of a recall on a regular basis (eg, every week or month). Then it is up to negotiations with the authorities if they regard a recall to have been satisfactory, which to a large extent depends on the severity of the risk, occurrence probabilities and the product in question. While a recall ratio of 85 to 90 per cent of consumer products is quite high, it could be deemed not sufficient for medical devices or automotive products. Experience shows that authorities have taken a significant amount of cars out of service because consumers did not react to the recall campaign at the expected rate.

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

In case of a direct contractual relationship between a manufacturer and an end customer, the manufacturer will have to replace the defective good free of charge as long as affirmative defences against contractual claims (especially warranty claims) do not exist. If merely a component is defective, warranty claims will include dismantling and reinstallation costs according to the European Court of Justice's case law as long as the end customer is a consumer. If the end customer is a business, the latter – currently – only applies if the manufacturer was negligent. However, this peculiarity of German law will probably become history at the end of 2017 as the German parliament (the Bundestag) set out a new law that will change the relevant provisions. German courts and legal literature will certainly see if these legal amendments may be avoided by contractual agreements or else.

The general limitation on sales contracts is two years.

There does not exist German case law stating that a producer or manufacturer has to repair or replace goods free of charge if there do not exist contractual warranty claims. However, given that a manufacturer will have to make sure that a product risk will definitely be eliminated, it will have to repair or replace its product when the end user is a consumer and there is a likelihood that the consumer otherwise will continue to use a defective and hazardous product. A duty to replace or recall defective products may not arise if a warning is deemed sufficient to eliminate the risk, warranty claims have elapsed and it is safe to assume that the customers (eg, business customers) will not continue to use the defective products.

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

If the circumstances require a recall of a defective product, the manufacturer is seen as having violated its duty to maintain public safety. As a consequence, the manufacturer will have to bear all claims of persons harmed by the product if their damages are caused by the manufacturer's failure to undertake a recall or other (appropriate) corrective actions. Such claims can contain material as well as immaterial damages.

In case of personal injury the manufacturer will face criminal charges. If a court finds that the board members had knowledge or should have known that a recall was the only appropriate means of eliminating a danger, it could assume intentional conduct. In case of death of a person, the penalty could be imprisonment for up to 15 years.

Update and trends

While the following case is not particularly a product recall topic, but rather a general liability issue, it is relevant in product recall cases, especially when the product risk has materialised and human beings have been killed.

In July 2017, the German parliament amended the rules for damages for pain and suffering and to allow claims for 'appropriate' damages for pain and suffering caused to survivors who were close to the deceased. Such closeness is deemed to exist when the claimant is the spouse, parent or child of the deceased. Until then, survivors were able to bring a claim for damages for pain and suffering only if they themselves suffered personal injury because of the death of a close person (eg, when suffering a shock on the news of someone's death).

The discussion about whether 'class actions' should be introduced into the German remedial system has been revived with the VW-diesel scandal, although it is not a pure recall topic. Consumer protection organisations renewed their criticism that single customers (still) abstain from pursuing their rights owing to legal (and cost) uncertainties. This issue could be tackled by the introduction of class actions, but the discussion on how this remedy could work, which entities should be entitled to make use of it and to what extent a decision should be binding is ongoing.

We have seen a rise in recalls for products for children and babies (nutrition, clothes and toys) as well as bio foodstuff. Furthermore, the automotive sector, an 'evergreen' in product recalls, has seen spectacular recalls as well as convenience recalls over the past 12 months, and this trend will probably continue.

Authorities are legally allowed to impose fines from €10,000 for refraining from taking corrective actions up to €100,000 for refraining from undertaking a product recall irrespective of the injury of persons.

Authorities' powers

19 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?

Authorities are legally allowed to issue a variety of remedial or corrective orders. Among the protective or remedial measures they may take are product quality tests, public warnings, distribution prohibitions, a recall or destruction of the product. Since the ProdSG belongs to the area of law for the prevention of hazards, authorities must abide by certain principles (required by constitutional law) such as suitability and reasonableness of the measures taken.

However, the primary focus of public and civil laws for controlling and eliminating a product risk are the manufacturer, importer and distributor. If they have taken the appropriate steps to control a product risk, authorities will have to very carefully assess whether authoritative action is indeed necessary.

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

As mentioned before, German authorities are entitled to take a wide variety of measures to avoid and eliminate product risks. That includes issuing information to suppliers or dealers and issuing warnings to the public in respect of substantial product risks in case the producer, importer or distributor did not take appropriate action in time.

Consumers will find warnings and information concerning other remedial measures on government websites, and there exist certain sites that feature the opportunity to post online reports or remarks. The authorities would be potentially liable in civil law – even if public liability is difficult to establish – for any unlawful content to the extent it caused damages to a private person or entity.

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

The authorities may order a product recall if no less severe measure is sufficiently suitable to fully control a specific product risk (eg, amended warnings or additional labelling). Since the authorities need to follow the test of reasonableness in principle, as a first step they are usually bound to order the manufacturer, importer or distributor to recall the product. In the event the addressee does not comply with the order or the product poses a serious risk to the health or safety of human beings on the basis of a reasonable risk assessment, the authorities may not only be legally allowed to, but even have an obligation to conduct or organise a recall themselves.

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

As a matter of general principle in public law for the prevention of hazards, costs for authoritative action incurred in the lawful control or elimination of risks in lieu of the responsible party may be recovered from this party by way of administrative order. However, the expenses should have been reasonably incurred for suitable and necessary parts of the corrective actions, which is litigable in court.

23 How may decisions of the authorities be challenged?

The competent authorities in cases of prevention or elimination of product risks are state authorities. This means that legal procedures differ from state to state. In some states it is mandatory within the regulatory framework to challenge the decisions of authorities by an objection which must be addressed to the authority that has issued the decision. During the course of proceedings, either the issuing or supervisory authority may affirm, amend or even reverse the initial order. If the administrative bodies fully stand by or partly confirm their decision, the affected party can file public law litigation in the administrative court system, which may comprise trial and tiered appeal processes.

As some states abolished the need for administrative review proceedings, immediate public law litigation before the court is allowed.

The formal challenge as well as litigation generally have a suspensive effect; however, the administration may order the immediate enforceability of the challenged order, in which case such enforceability itself may be subject to administrative or judicial review.

In cases of utmost urgency, manufacturers or others who are affected by directives from authorities have the opportunity to initiate accelerated litigation to seek a temporary order or preliminary injunctive relief. Within this summary process, the judicial examination focuses on the matter of urgency. The administrative court will assess whether the interests of the affected party or public interests are to prevail in the context of the extent and severity of the product risk. In practice this kind of accelerated process is quite usual in Germany.

Implications for product liability claims

24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

The administrative order does not have any prejudicial effect on any potential civil law obligation or dispute. The intention of the legislation in respect of the laws on prevention of hazards is to avoid or mitigate product risks to the public and consumers in particular, and to grant the government decisive and extensive measures to protect public safety. Subject to the risk assessment of the authorities, issuing warnings or conducting a recall may be unrelated to a specific manufacturer of an affected family of products, or unrelated to specific products of the total production lots. There may be no way to identify defective products of a larger production series within reasonable time and expense. Eventually, the distribution chain may not be immediately known, and authorities may act on preliminary and incomplete information. Thus, warnings or recalls simply may have an impetus that does not help a potential plaintiff in litigation.

The civil law liability (product liability) is determined by the requirements of the applicable tort and strict liability regimes and will require that the claimant provides, among other things, evidence that the product was defective and caused the alleged damage.

25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

German civil procedure law does not recognise any kind of discovery process or a pretrial discovery phase in general. As a consequence, neither party has procedural pre-litigation means to compel the opposing party to either disclose any type of documents or records. This is in consideration of the 'principle of provision', meaning that the parties to a litigation need to fully state their case and provide evidence for all disputed facts; the principle of disposition is to put the proceedings into the hands of the parties themselves and the parties decide what facts and documents to provide from their side. Under certain limited circumstances (but only within the confines of a trial) the court may order a party to provide specific documents it deems to be decisive.

In product liability litigation, therefore, the plaintiff needs to provide evidence of the defect and causation, at least, without recourse to any records that may be in possession of the other party. However, civil procedure law recognises certain rules that may partly relieve the plaintiff from the burden of proof or even reverse it.

In contrast to civil procedure, criminal courts and prosecutors are indeed entitled to force disclosure of internal information of the manufacturer (eg, by seizure). For this reason claimants sometimes initiate criminal investigations against potential defendants before suing them in civil litigation, as the German law of civil proceedings recognises a right to access records of the prosecution as long as a legal interest exists.

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