Alerts on the Safety Gate European rapid alert system – options for affected economic operators

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baua: Focus

Safe products are vital to consumers' safety and health on the European Union (EU) internal market. In Germany, the aim of ensuring products are safe has been supported above all by the transposition of the various European directives concerning technical products. This has been done with the Product Safety Act (Produktsicherheitsgesetz, ProdSG) in conjunction with the Market Surveillance Act (Marktüberwachungsgesetz, MüG) and their associated ordinances and implementing acts, which govern the safety characteristics of products from toys to heavy machinery. Effective market surveillance is required if these pieces of legislation are to be observed and implemented. Only this makes it possible to ensure that those who use products are protected against safety and health hazards. This publication provides information for economic operators about the options open to them if they are affected by a notification.

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1 Introduction

Under the Market Surveillance Act and the Product Safety Act, the Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, BAuA) is tasked with supporting the authorities responsible for market surveillance in Germany's federal states in the performance of their duties. Furthermore, BAuA is the national Contact Point for the EU's RAPEX rapid alert system for dangerous products. The present publication, which complements other BAuA publications on product safety, is to be viewed against this background.

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Apart from the many safe products, dangerous and non-compliant products also find their way onto the European internal market every year. If such products come to light in one of the European Union's Member States or the non-EU states Iceland, Norway, and Liechtenstein, their details are published on the RAPEX system, also known as "Safety Gate". The system allows the EU states to share information about problems with products so they can take appropriate protective measures. In addition, consumers can also find out about these products in the system's public area. They are only able to do this if dangerous products are notified by the authorities in the first place. This baua: Focus, which is intended for economic operators and other interested parties, explains how notifications are submitted, who submits them, and how it is possible to respond to them.

2 What is the European rapid alert system?

The Rapid Exchange of Information System (RAPEX) or Safety Gate is the EU's rapid alert system for dangerous consumer products as provided for in Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (GPSD). Furthermore, the Directive applies to consumer products and products for professional use subject to Regulation (EU) 2019/1020 that are covered by the EU's harmonisation legislation. Measuring instruments and marine equipment may be mentioned as examples of professionally used products.

3 What are the aims of the rapid alert system?

The rapid alert system provides information about the hazards presented by products, as well as the measures adopted to prohibit or restrict the use of dangerous products on the European internal market. As a rule, notifications are submitted about products that pose a serious risk. These "RAPEX alerts" or "RAPEX notifications", as they are known, also include information about product withdrawals and recalls. At the same time, the rapid alert system records both the measures adopted by national market surveillance authorities and the voluntary measures taken by manufacturers and retailers.

The aims of the system are to promote reciprocal information sharing between the authorities across Europe and the European Commission, and to alert the public to dangerous products. As a result, Safety Gate makes an important contribution to product safety and consumer protection on the EU internal market.

4 What are the legal foundations for product safety and market surveillance?

Issues relating to product safety and market surveillance are governed by European internal market law. The relevant European regulations, directives, etc. have been transposed into national law in Germany. A number of examples of important legislation in this field are listed in Table 1 below.

Tab. 1 Legal foundations for product safety and market surveillance (source: BAuA)

European law	National law
Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC Commission Implementing Decision (EU) 2019/417 of 8 November 2018 laying down guidelines for the management of the European Union Rapid Information System 'RAPEX' established under Article 12 of Directive Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (in force since 16 July 2021	Product Safety Act (ProdSG) Ordinances and implementing acts to the ProdSG for individual product groups, e.g. First Ordinance to the Product Safety Act[2] (electrical equipment), Second Ordinance to the Product Safety Act[3] (children's toys), Sixth Ordinance to the Product Safety Act[4] (simple pressure vessels), Personal Protective Equipment Implementing Act[5] Specialised legislation, e.g. Act on Medical Devices[6] Market Surveillance Act (MüG) (in force since 16 July 2020)

[2] First regulation of the Product Safety Act, 1. ProdV.
[3] Second regulation of the Product Safety Act, 2. ProdV.
[4] Sixth regulation of the Product Safety Act,, 6. ProdV.
[5] PSA-Implementing Act, PSA-DG.
[6] Medical Devices Act, MPG

Table 2 illustrates the range of market surveillance within the scope of Regulation (EU) 2019/1020, listing some of the 33 product sectors that are covered, the harmonised EU legislation that governs them, the government departments responsible for each sector, and the authorities responsible for their surveillance in Germany.

Tab. 2 Market surveillance within the scope of the Market Surveillance Regulation (selected sectors)

Product sectors and harmonised EU legislation		Responsible department	Market surveillance authority
3. Toys	2009/48/EC	BMWi[7]	Federal state market surveillance authorities
4. Personal protective equipment	EU Nr. 2016/425	BMAS[8]	Federal state market surveillance authorities
7. Simple pressure vessels and pressure equipment	2014/68/EU	BMAS	Federal state market surveillance authorities
8. Transportable pressure equipment	2010/35/EU	BMVi[9]	Federal state market surveillance authorities, BAM[10], EBA[11]
9. Machinery	2006/42/EC	BMAS	Federal state market surveillance authorities
10. Lifts	2014/33/EU	BMAS	Federal state market surveillance authorities
16. Appliances burning gaseous fuels	EU Nr. 2016/426	BMAS	Federal state market surveillance authorities
19. Radio equipment	2014/53/EU	BMWi	Federal Network Agency[12]
27. Motor vehicles and tractors	(EU) Nr. 168/ 2013; (EU) Nr. 2018/858; (EU) Nr. 167/2013	BMVI	KBA[13]

(Source: Federal Network Agency) Date: 19 March 2020

[7] Federal Ministry for Economic Affairs and Energy (Bundesministerium für Wirtschaft und Energie)
[8] Federal Ministry of Labour and Social Affairs (Bundesministerium für Arbeit und Soziales)
[9] Federal Ministry of Transport and Digital Infrastructure (Bundesministerium für Verkehr und digitale Infrastruktur)
[10] Federal Institute for Materials Research and Testing (Bundesanstalt für Materialforschung und -prüfung)
[11] Federal Railway Authority (Eisenbahn-Bundesamt)
[12] Bundesnetzagentur, BNetzA
[13] Federal Motor Transport Authority (Kraftfahrt-Bundesamt)

4.1 Further information

A detailed list of the product sectors covered, including the relevant harmonised EU legislation and the legal acts that transpose it at the national level, will be found on the home page of the German Market Surveillance Forum (Deutsches Marktüberwachungsforum, DMÜF), which can be viewed at:
www.bundesnetzagentur.de/DE/Sachgebiete/Telekommunikation/Unternehmen_Institutionen/Technik/DMUEV/DMUEF-node.html

5 When and how is a notification submitted?

The notification of a product to the Safety Gate system begins with the market surveillance authorities that have technical and territorial jurisdiction. Pursuant to Section 25 of the Product Safety Act, they carry out checks on whether products meet the necessary legal and safety requirements, those set out in the Product Safety Act for example. The authorities do this by examining product samples, in response to complaints from the public, or on the basis of declarations received from economic operators themselves pursuant to Section 6 (4), (5), and (6) of the Product Safety Act. Irregularities are initially identified by checking products' documentation (formal non-compliance) and, if necessary, by carrying out physical inspections and laboratory tests (non-compliance).

The market surveillance authorities then adopt measures if they have justified reason to suspect that legal and technical requirements are not being fulfilled (compulsory measures). In addition, economic operators who have placed products on the market are able to take measures at their own initiative (voluntary measures).

Where a safety defect is detected, for example where there is a risk of electric shock, the market surveillance authority conducts an appropriate risk assessment. This involves the calculation of a risk level using the risk assessment method for Safety Gate/RAPEX. The method is described in the RAPEX Guidelines, which can be found at:
https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32019D0417&from=EN

In addition to the Guidelines, the Risk Assessment Guide (RAG) published by the European Commission is available at: *https://ec.europa.eu/rag*

Figure 1 depicts the risk assessment process as a flow chart. At the end of the procedure, the product's risk is classified at one of the four risk levels provided for: serious, high, medium, or low.

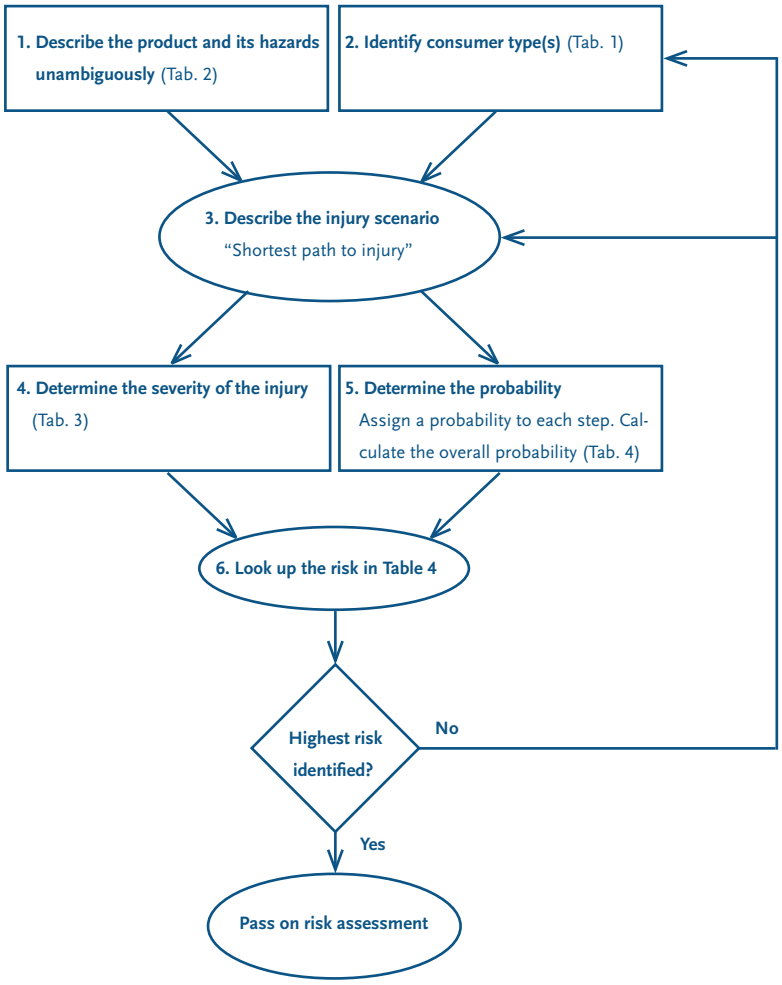

Fig. 1 Risk assessment using the Safety Gate/RAPEX method

In principle, the market surveillance authority is required to submit a notification to the rapid alert system if the following notification criteria set out in the General Product Safety Directive (GPSD) are fulfilled:

- Article 12 of the GPSD and Article 20 of Regulation (EU) 2019/1020
  - · Product covered by GPSD or Regulation (EU) 2019/1020
  - · Risk level: "serious risk"
  - · Cross-border effects: the reason for the measure lies outside German territory or the effects of this measure will reach beyond German territory.
  - · "Voluntary measure" or "compulsory measure"
- Article 11 of the GPSD
  - · Product's GPSD risk level is lower than serious, i.e. high, medium, or low risk
  - · Cross-border effects: the reason for the measure lies outside German territory or the effects of this measure will reach beyond German territory. The same applies analogously for all the Member States.
  - · "Compulsory measure"

In its RAPEX Guidelines, the European Commission details further types of notification and the criteria for their use. Figure 2 sets out the decision-making matrix for notifications to the rapid alert system.

Type of risk	Product covered by GPSD	Product covered by Regulation (EC) 765/2008; new: Regulation (EU) 2019/1020	Measure adopted	Cross-border effect	Insufficient identification information	Information involving new risks	Notification type
Serious risk	yes	no	Compulsory and voluntary	yes	no	no	**Article 12 of the GPSD**
	yes	no	Compulsory and voluntary	no	no	yes	**Article 11 of the GPSD**
	no	yes	Compulsory and voluntary	yes	no	no	**Article 22 of Regulation (EC) 765/2008; new: Article 20 of Regulation (EU) 2019/1020**
	Indistinctly		Compulsory and voluntary	yes	yes	no	**"For information"**
	Indistinctly		Compulsory and voluntary	nein	no	no	**Information to ICSMS** RAPEX-notification encouraged
Lower risk	yes	no	Compulsory measures	yes	no	no	**Article 11 of the GPSD**
	yes	no	Voluntary measures	yes	no	no	**"For information"**
	no	yes	Compulsory and voluntary	no	no	no	**Article 23 of Regulation (EC) 765/2008; new: Article 34 of Regulation (EU) 2019/1020** RAPEX-notification encouraged
Pending	no	no	no	no	no	no	**"For information" (if relevant)**

Fig. 2 Decision-making matrix for the notification procedure

(Source: based on Commission Implementing Decision (EU) 2019/417 of 8 November 2018 laying down guidelines for the management of the European Union Rapid Information System 'RAPEX' established under Article 12 of Directive 2001/95/EC on general product safety and its notification system, OJ L 2019 L73/124, p. 12)

DEFINITION OF RISK IN THE PRODSG

Point 22 of Section 2 of the Product Safety Act defines risk as "the combination of the likelihood of a hazard and the severity of the potential damage". Depending on the product and the type of hazard, however, translating this intrinsically unambiguous definition into practice in the authorities' work is a multifaceted and not always easy task. For example, levels of hazardous substances that exceed limit values can be detected using laboratory techniques in accordance with the relevant protocols. Furthermore, the assessment of a product's risk is straightforward if the context for its use is clearly defined (e.g. chromium VI levels in leather gloves). By contrast, it is more difficult to assess product risks where they can only be identified by analysing the causal chain of which they are the outcome and where account has to be taken of the product's foreseeable use by its users (e.g. live parts exposed due to a mechanical defect in a product's insulation).

5.1 Selected examples from the RAPEX Guidelines):

Example 1: Socket protectors

"This case deals with socket protectors. These are devices that users (parents) put into the electrical socket outlets to stop small children from accessing live parts by putting a long metal object into one of the holes in the outlet and getting a (fatal) electric shock."

Determination of risk(s)

Injury scenario	Injury type and location	Severity of injury	Probability of injury		Overall probability	Risk
Protector is removed from the socket, which becomes unprotected. Child is playing with thin conductible object, which can be inserted into the socket, accessing high voltage and is electrocuted.	Electrocution	4	Removal of protector Not noticing the removal of protector Child is playing with thin conductible object Child is unattended when playing Child inserts the object into the socket Access to voltage Electrocution due to voltage (without circuit interrupter)	9/10 1/10 1/10 1/2 3/10 1/2 1/4	27/160 000 > 1/10 000	Serious risk
Protector is removed from the socket, which becomes unprotected. Child is playing with thin conductible object, which can be inserted into the socket, accessing high voltage and sustains shock.	Burns 2nd degree	1	Removal of protector Not noticing the removal of protector Child is playing with thin conductible object Child inserts the object into the socket Access to voltage Child is unattended when playing Burn due to electric current (without circuit interrupter)	9/10 1/10 1/10 3/10 1/2 1/2 3/4	81/160 000 > 1/10 000	Low risk

Fig. 3 Excerpt from the examples of risk determination given in the RAPEX Guidelines (Source: Commission Implementing Decision (EU) 2019/417 of 8 November 2018 laying down guidelines for the management of the European Union Rapid Information System 'RAPEX' established under Article 12 of Directive 2001/95/EC on general product safety and its notification system, OJ L 2019 L73/124, p. 56)

Example 2: Folding chair

"A folding chair has a folding mechanism constructed in such a way that the user's fingers can get trapped between the seat and the folding mechanism. This can lead to fractures or even loss of one or more fingers."

Determination of risk(s)

Injury scenario	Injury type and location	Severity of injury	Probability of injury		Overall probability	Risk
Person is sitting on chair, wants to move the chair and tries to lift it by gripping the chair at the rear part of the seat, finger gets caught between seat and link	Loss of digit	3	Sitting on chair	1	1/6 000	High risk
			Moves the chair while sitting	1/2		
			Grips chair at rear part while moving	1/2		
			Chair partially folds, creating a gap between the backrest and seat	1/3	> 1/10 000	
			Finger is between backrest and seat	1/5		
			Finger gets caught	1/10		
			Loss of (part of) finger	1/10		

Fig. 4 Excerpt from the examples of risk determination given in the RAPEX Guidelines (Source: Commission Implementing Decision (EU) 2019/417 of 8 November 2018 laying down guidelines for the management of the European Union Rapid Information System 'RAPEX' established under Article 12 of Directive 2001/95/EC on general product safety and its notification system, OJ L 2019 L73/124, p. 55)

6 Where is an alert published?

The European Commission publishes an overview report about the dangerous products that have been notified by the Member States on its Safety Gate internet portal every Friday. These reports allow consumers to find out whether a product they have come across is potentially dangerous or not. The same applies if a retailer wishes to sell or import products. Many businesses also use Safety Gate alerts to gather fundamental information about possible product risks, for example because they intend to draw up a risk assessment for one of their own products. The reports are available at: *https://ec.europa.eu/safety-gate-alerts*

In parallel, product recalls, product alerts, prohibition orders, and other information about dangerous products that are regulated by the Product Safety Act or other legislation and of which it has become aware are published by BAuA in its Dangerous Products in Germany database. The portal can be found at: *www.rueckrufe.de*

Dangerous Products in Germany also features extracts from the European Commission's weekly Safety Gate reports in German. For example, alerts about affected products and/or economic operators from Germany, as well as notifications submitted by German market surveillance authorities can be found in the database.

7 What information does a RAPEX alert include?

The chief aims of a Safety Gate alert are to provide information about current risks and make it possible for affected products to be identified unambiguously. The market surveillance authority therefore gathers the following information and specifies what information is to be made available to the public. Among other things, this includes:

- a description of the product (product category, product name, type)
- the batches or delivery and production dates covered by the notification
- the applicable legislation and standards
- a risk description
- traceability data (manufacturer, exporter(s), importer(s), distributor(s), and retailer(s))
- measures

Figure 5 shows an example of a published Safety Gate alert:

Notification number 0002/11

Published on 05/01/2011 in web report Report-2011-002

Print | Back to report

Type of risk	Electric shock Risk of electric shock The equipment casing and the pot may become live owing to a fault in the control knob. If there is inadequate protective earthing via the domestic power supply there is a risk of electric shock.
Country	**Germany**
Notification number	**0002/11**
Category	Electrical appliances

Product

Hide details of the Product

Description Electric fondue set with heating ring and fondue pot; pot: stainless steel with black lid, lower part black

Description of the packaging

Brand

Not known

Name

Not known

Type/Number of model

KH 1090, Item No 421639

Is the product counterfeit?

Not known

Fig. 5 RAPEX alert 0002/11
(Source *https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=viewProduct&reference=0002/11&lng=de*, *Stand 12.05.2021*)

8 Who is responsible for an alert?

The market surveillance authority in the notifying Member State that has submitted the notification is exclusively responsible for the alert and its contents. The authority bears full responsibility for the information communicated, even though the European Commission has published the alert on its website. Internal consultations are consequently carried out within the authorities prior to publication, usually with organisational support from the national Contact Points. Section 4 of the Market Surveillance Act regulates the competences for and collaboration on market surveillance activities in Germany.

In principle, pursuant to Section 25 (1) of the Product Safety Act, market surveillance in the fields governed by the Act is a matter for the authorities responsible under the laws of Germany's federal states. At the federal level, competences have been granted to individual federal authorities, such as the Federal Motor Transport Authority, the Federal Network Agency, the Federal Maritime and Hydrographic Agency (Bundesamt für Seeschifffahrt und Hydrographie, BSH), the Federal Institute for Materials Research and Testing, and the Federal Railway Authorit).

8.1 Further information

Market surveillance of technical products
The Information and Communication System on Market Surveillance (ICSMS) is a comprehensive communication platform for the market surveillance of non-food products and the mutual recognition of goods.
https://webgate.ec.europa.eu/icsms/public/consumer.jsp?locale=de

Market surveillance authorities/bodies/institutions in Germany within the scope of Regulation (EC) 765/2008 (German)
www.bundesnetzagentur.de/SharedDocs/Downloads/DE/Sachgebiete/Telekommunikati-on/Unternehmen_Institutionen/Technik/DMUEF/Behoerden_Gremien_uebersicht.pdf

9 What role does BAuA play in the notification procedure as the German Contact Point?

Pursuant to the Market Surveillance Act and the Product Safety Act, BAuA is not a market surveillance authority and does not exercise either legal or technical supervision over the market surveillance authorities. As the national Contact Point, BAuA reviews notifications submitted by German market surveillance authorities to ensure they are complete and consistent. It also reviews market surveillance authorities' reactions to and appeals against previously published notifications. BAuA subsequently forwards the validated notifications to the European Commission for final validation. BAuA expressly does not carry out any technical checks. In addition, under Section 19 (1) of the Market Surveillance Act, BAuA supplies information to the public, preferably via electronic channels, about the knowledge at its disposal concerning products that pose risks to human safety and health. BAuA operates the Dangerous Products in Germany database (*www.rueckrufe.de*) for this purpose.

COMPLETENESS AND CONSISTENCY REVIEWS

In accordance with the first sentence of Section 18 (4) of the Market Surveillance Act, "BAuA reviews the completeness and consistency of the notifications it receives. The completeness review is intended to ascertain whether all documents, the properly completed authority notification form, and the information and other data that substantiate the authority's assessment have been included (reference may be made to Part II (3.2.1) and (3.2.2) of the RAPEX Guidelines in this respect). What is required is a purely formal completeness review, not a qualitative evaluation of the market authority's assessment. When the consistency review is carried out, it is assumed that the notifying authority's submission is correct, and it is merely examined whether this submission justifies the RAPEX notification and the right notification procedure has been initiated; BAuA therefore purely reviews whether the submission is plausible on the basis of the assessment made by the market authority."

(Source: quotation from the unpublished legal opinion "Rechtsstaatliche Grundlagen der Veröffentlichungspraxis im RAPEX-System" (Rule-of-Law Foundations for Publication Practice in the RAPEX System) by Prof. Dagmar Gesmann-Nuissl")

10 How can an alert be changed or removed?

An alert can only be withdrawn from Safety Gate at the application of the market surveillance authority in the notifying Member State that is responsible for it. According to the RAPEX Guidelines, this is possible if the notification criteria are no longer fulfilled or there is evidence the product is no longer being marketed. One example of this would be where a compulsory measure has been challenged and is consequently no longer legally valid and/or no longer has binding effect; another would be where a risk assessment proves retrospectively to have been incorrect. In consequence, the notification criteria would no longer be fulfilled.

Since BAuA is the German national Contact Point and not a market surveillance authority, it is unable to remove, suspend, or change alerts. These decisions can only be taken by the market surveillance authorities with technical and territorial jurisdiction. This is true both in Germany and in the other Member States.
Should your business be affected by a Safety Gate alert and you have not yet had the opportunity to put your case, contact the market surveillance authority with technical and territorial jurisdiction over your product to discuss the further action to be taken. It is incumbent upon the market surveillance authorities to assess the facts of the matter at their own discretion. You may communicate objections, clarifications, or supplementary information concerning an alert via BAuA to the European Commission in the form of a "reaction".

The responsible national market surveillance authority can be found by searching in ICSMS: *https://webgate.ec.europa.eu/icsms/public/authoritySearch.jsp?locale=de*

Where Safety Gate alerts have been submitted from other Member States, it may be best to get in touch with the national Contact Point of the Member State in question first of all: *https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/docs/rapex_contact_points_en.pdf*

11 Conclusions

The Safety Gate (RAPEX) rapid alert system quickly disseminates alerts about dangerous products, ensures transparency, and supplies information for interested parties all over Europe

about measures that have been adopted, such as product recalls and withdrawals. The responsibility for notifications lies with the market surveillance authorities, whose performance of their duties is supported by BAuA as the German national Contact Point. Consumers, businesses, and other economic operators can find out about dangerous products from the European Commission's Safety Gate portal or the Dangerous Products in Germany database operated by BAuA. Businesses affected by alerts can contact the market surveillance authority with technical and territorial jurisdiction over their product to discuss the further action to be taken.

The German Contact Point at BAuA will be happy to assist if you have any questions about the notification procedure:
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Questions about publications in BAuA's Dangerous Products in Germany database should be sent to:
rueckrufe@baua.bund.de

Suggested citation
Engelbach, Christian; Bleyer, Tobias; Blume, Jochen: 2021. Alerts on the Safety Gate European rapid alert system – options for affected economic operators. baua: Focus.

English translation. German original available: doi:10.21934/baua:fokus20210502

Gender-neutral language is used in this publication. Where this is not possible or would detract from the readability of the text, terms used to refer to persons include all genders.

Imprint | Publisher: Federal Institute for Occupational Safety and Health (BAuA), Friedrich-Henkel-Weg 1-25, 44149 Dortmund | Telephone: +49 231 9071-2071, mail to: *info-zentrum@baua.bund.de*, Internet: *www.baua.de*, Design: R. Grahl | DOI:10.21934/baua:focus20210809 | November 2021

baua: Federal Institute for Occupational Safety and Health