

Product Risk Radar

General Product Safety Regulation: A new era of product safety for the EU

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In brief

The **General Product Safety Regulation ((EU) 2023/988)** (“GPSR”) applies from 13 December 2024. The GPSR replaces the General Product Safety Directive (2001/95/EC) (“GPSD”). The new GPSR looks set to be one of the most significant updates to the EU’s product regulatory landscape in modern history – making substantial amendments to the GPSD, which has been in force for more than two decades. For businesses selling products in Northern Ireland, it is important to note that the GPSR applies in NI (but not the rest of the UK) given arrangements put in place post Brexit (see [here](#) for OPSS guidance on this point).

The objective of the GPSR is to improve the functioning of the internal market while providing for a high level of consumer protection to EU consumers in respect of products they purchase, both in store and online, with the European Parliament also calling out in its press release (see [here](#)) the increased protection of vulnerable consumers, like children and persons with disabilities. The GPSR will also enhance market surveillance of dangerous products in the EU and the GPSR aims to improve the effectiveness of any recalls of such products.

As a regulation, this legislation is directly applicable, leaving little room for disparities across EU countries. The Regulation is relevant for any economic operator which is in any way involved in the sale of products onto the EU market; even those who are not themselves established within the EU will need to comply with the new rules.

The new GPSR does not prevent the sale of products which are in conformity with the GPSD and were placed on the market before 13 December 2024.

In depth – what are the implications of the reform?

The GPSR aligns the existing GPSD with the latest developments in digitalisation, in line with the European Commission’s (“EC’s”) New Consumer Agenda of 2020. The GPSR makes a number of changes to the existing product regulatory landscape, including:

1. Responsible Person

The GPSR contains a requirement for a “responsible person” to be established within the EU before products can be placed on the EU market, likely with a view to ensuring that there is always an EU entity

General Product Safety Regulation: A new era of product safety for the EU

that can be held accountable for any product-related issues. That responsible person will have various obligations, including: (a) if requested, providing a market surveillance authority with all information and documentation necessary to demonstrate the conformity of a product; and (b) regularly checking that the product complies with appropriate technical documentation. The GPSR also requires that details of the economic operator which is the responsible person are included on the product or on its packaging, the parcel or an accompanying document.

2. Online Marketplaces

The EC considers that growth of ecommerce has decreased the effectiveness of the GPSD. This is particularly relevant in circumstances where 73% of consumers bought products online in 2021 (compared to 50% in 2014). Accordingly, the GPSR recognises that providers of online marketplaces play a crucial role in the supply chain, allowing economic operators to reach a greater number of consumers, and therefore also in the product safety system. As such, the GPSR seeks to regulate this area by including specific requirements in respect of online marketplaces and online sales.

In particular, the GPSR includes various requirements for providers of online marketplaces (in part, building on requirements in the EU Digital Services Act (Regulation 2022 / 2065)) to, for example, (i) identify and register a single contact point for market surveillance authorities; (ii) design and organise their marketplace so that traders can provide information to consumers including warning and safety information; and (iii) directly notify affected consumers who bought through their interfaces a product which is the subject of a product safety recall or where certain information has to be brought to the attention of consumers to ensure the safe use of a product. Online marketplaces also have obligations to inform market surveillance authorities, via the Safety Business Gateway, about dangerous products that they have made available on their online interface (of which they have actual knowledge), and to report accidents as set out in further detail below.

3. Accident Reporting

Whilst earlier drafts of the GPSR required reporting of an accident related to the safety of a product by an economic operator within 2 business days, the final version of the GPSR has rowed back from this position, instead mandating reporting of an accident via the Safety Business Gateway without undue delay from knowledge of that accident. Whilst the GPSR does not provide any definition of “accident”, it does outline a relatively high threshold for the severity of such accident to warrant a notification. A report would need to be made in respect of an accident that “resulted in an individual’s death or in serious adverse effects on that individual’s health and safety, permanent or temporary, including injuries, other damage to the body, illnesses, and chronic health effects”.

The GPSR sets out separate accident reporting obligations for online marketplaces, with a different threshold for the making of a report. In particular, a report must be made in respect of an accident which has resulted in a “serious risk or actual damage to the health or safety of a consumer, caused by a product made available on their online marketplace and inform the manufacturer thereof”. This comparatively lower threshold for the reporting of accidents could lead to some inconsistencies in terms of which accidents are reported by economic operators vs. online marketplaces.

General Product Safety Regulation: A new era of product safety for the EU

4. Product Recalls

The improvement of the effectiveness of product recalls across the EU has been a key objective for the EC in the reform of the GPSD. Accordingly, the GPSR sets out granular requirements for the conduct of product recalls, details which we would generally expect to see in guidance rather than legislation itself.

Under the GPSR, economic operators such as manufacturers, distributors, and importers will have an obligation to act to recall products, where necessary, with online marketplaces also being obliged to cooperate to ensure effective product recalls. Detailed provisions as to the contents and form of the recall notice have also been included, presumably for standardisation purposes. The EC carried out a short consultation on a recall notice template. The final template was adopted on 24 May 2024 (see [here](#)).

5. New Technologies

The GPSR seeks to ensure that the EU's product safety regime can be applied effectively to 21st century developments and can respond quickly to new and emerging challenges, including those posed by connected products and software updates as well as the evolving functionalities of AI-powered products. To address this issue, the GPSR adopts newly improved definitions; for example, "product", now expressly includes a reference to items which are interconnected to other items.

The GPSR also includes a list of points for consideration when assessing the safety of products, including:

- the effect of the product on other products, including the interconnection of those products;
- the appropriate cybersecurity features necessary to protect the product against external influences, including malicious third parties, where such an influence might have an impact on the safety of the product, including the possible loss of interconnection; and
- the evolving, learning and predictive functionalities of the product.

The GPSR also addresses responsibility for product safety where a substantial modification is made to a product; the person performing that substantial modification will be considered a "manufacturer" of that product.

6. Safety Gate

Earlier this year, the EC consulted on a short draft Implementing Regulation intended to explain in more detail how Safety Gate would enable "consumers and other interested parties" (this is not limited to purchasers) to inform the EC about products that might present a risk to their health or safety. The Implementing Regulation was published in the Official Journal of the European Union in June 2024 (see [here](#)).

As stated in the Implementing Regulation, the EC plans to use an automated filtering system to distinguish between issues which raise safety concerns and those which do not. Information about safety issues would then be forwarded to relevant Member States (apparently without the EC taking other steps to verify that the information provided genuinely relates to product safety).

General Product Safety Regulation: A new era of product safety for the EU

On 27 August 2024, the EC published a Delegated Regulation on the management of the Safety Gate Rapid Alert System regarding the operating rules of the Safety Gate system, including guidance for Member States on assessing risk (see [here](#)). **This Delegated Regulation (2024/3173)** applies from 13 December 2024. The Delegated Regulation is intended to update the RAPEX guidelines in Implementing Decision 2019 / 417. It contains a detailed list of information that Member States should include when notifying via the Safety Gate system (including shipping and other documents where manufacturers and exporters of the product are located outside the EU and test reports). Further, the Delegated Regulation provides that Member States in some cases should take into account public interests other than health and safety when assessing risk (such as the environment, energy resources or property). It also contains guidance on circumstances in which risks shall be presumed to be serious (e.g. small parts issues for toys for children under 36 months, highly flammable fancy dress costumes for children or electrical products with defective components that can lead to electric shock or fire).

7. Penalties

Whilst previous drafts of the GPSR proposed a maximum penalty equating to at least 4% of a company's annual turnover in the relevant Member State, the final version states that penalties must be “effective, proportionate and dissuasive”, but leaves to the discretion of Member States the decision as to what penalty would be appropriate.

What next?

Given arrangements in place following Brexit, the new GPSR will apply in Northern Ireland but not the rest of the UK.

Assuming that the new GPSR is not replicated in the rest of the UK as it reviews and updates its product safety regime (see [here](#) for the current developments being discussed in the UK), companies selling products on both the UK and EU markets could find themselves having to comply with two (different) sets of requirements.

Every company involved in the sale of products to the EU market must now ensure they are prepared for this new era of product safety in the EU. For further information on these developments and how they may affect your business, please do not hesitate to get in touch with any member of our team.

General Product Safety Regulation: A new era of product safety for the EU

Contacts



Kate Corby

Partner
London

+44 20 7919 1966
kate.corby
@bakermckenzie.com



Graham Stuart

Partner
London

+44 20 7919 1977
graham.stuart
@bakermckenzie.com



Ulrich Ellinghaus

Partner
Frankfurt

+49 69 2 99 08 251
ulrich.ellinghaus
@bakermckenzie.com



Andreas Neumann

Senior Associate
Frankfurt

+49 69 2 99 08 310
andreas.neumann
@bakermckenzie.com



Joanne Redmond

Senior Associate
London

+44 20 7919 1067
joanne.redmond
@bakermckenzie.com



Rachel MacLeod

Senior Associate
London

+44 20 7919 1364
rachel.macleod
@bakermckenzie.com



Phoebe Bruce

Associate
London

+44 20 7919 1117
phoebe.bruce
@bakermckenzie.com



Francesca Falsini

Associate
London

+ 44 20 7919 1000
francesca.falsini
@bakermckenzie.com