



WELCOME, WE WILL START SOON

PLEASE NOTE:

- *YOU ARE AUTOMATICALLY ON MUTE*
- *SUBMIT THE QUESTION TO THE Q&A*



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GENERAL PRODUCT SAFETY REGULATION

REGULATION (EU) 2023/988

General Product Safety Regulation



Regulation (EU) 2023/988

- On 12th June 2023, the [General Product Safety Regulation \(EU\) 2023/988 \(GPSR\)](#) entered into force.
- 13th December 2024, GPSR replaced ultimately the General Product Safety Directive 2001/95/EC.
- **The General Product Safety Regulation (GPSR)** updates and replaces the former General Product Safety Directive (GPSD) in response to emerging technologies, evolving business models, and the rise of **online marketplaces**. These changes have introduced **new challenges for product safety** and brought **new economic operators** into the EU market, such as online sellers and fulfilment service providers.
- Ensuring a high level of product safety is critical for both protecting consumers and maintaining trust in the internal market.
- The GPSR also repeals Directive 87/357/EEC, which previously addressed products that resemble foodstuffs.

Differences between Directive and Regulation



The key difference lies in how they are applied and enforced in EU member states

EU Regulation

- A regulation is **fully binding** on all EU member states.
- It **applies immediately and uniformly** across all member states without needing national laws to implement it.
- All member states had to comply **directly**.

EU Directive

- A directive sets out a **goal** that all EU countries must achieve.
- Each member state decides **how to achieve** the goal by adapting its own laws within a set deadline.
- **Flexibility in implementation**, through national legislation.

GPSR vs GPSD

The key changes

- GPSR is **directly applicable** across all EU Member States.
- It is **identical** across EU, which gives the **uniformity across EU**
- Introduces **new obligations** for Economic operators and Providers of an Online Marketplace
- Requires to appoint **a responsible economic operator based within the EU**
- Updates and **modernises the Safety Gate** - the European Union rapid alert system for unsafe consumer products (formerly known as RAPEX)

Framework of GPSR

- The objective of the new General Product Safety Regulation (GPSR) is to:
 - strengthen **safety requirements for products sold both online and offline**,
 - enhance **market surveillance** of unsafe products, and
 - improve **consumer protection**.
- **The GPSR applies to all products** made available or placed on the European market, except those explicitly excluded from its scope.* Unlike the previous General Product Safety Directive (GPSD), the new regulation clearly identifies and defines which products fall outside its scope.
- This includes **products that are not covered by Union harmonisation legislation or do not have specific EU safety requirements**.
- However, for **products subject to Union harmonisation legislation, the GPSR applies to aspects not specifically addressed by that legislation** (parts of Chapters I, III, IV, VI and VIII, i.a. related to: General provisions, Obligations of economic operators, Notification of dangerous products and Safety Gate Portal).

***Article 2(2):** Medicinal products, Food, Feed, Living plants and animals, Animal by-products and derived products, Plant protection products, Equipment on which consumers ride or travel, Aircraft referred to in Article 2(3), point (d) of Regulation (EU) 2018/1139, Antiques. It does not apply to products to be repaired or reconditioned prior to being used where those products are placed or made available on the market and are clearly marked as such.

GPSR

ECONOMIC OPERATORS

Economic Operators - *Article 3*



- **Manufacturer:** means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under that person's name or trademark;
- **Authorised Representative:** means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on that manufacturer's behalf in relation to specified tasks with regard to the manufacturer's obligations under this Regulation;
- **Importer:** means any natural or legal person established within the Union who places a product from a third country on the Union market;
- **Distributor:** means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;
- **Fulfilment Service Provider:** means any natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved, excluding postal services;
- **Economic Operator:** means the manufacturer, the authorised representative, the importer, the distributor, the fulfilment service provider or any other natural or legal person who is subject to obligations in relation to the manufacture of products or making them available on the market in accordance with this Regulation;
- **Provider of an Online Marketplace:** means a provider of an intermediary service using an online interface which allows consumers to conclude distance contracts with traders for the sale of products;

Obligations of Manufacturers, *Article 9*

- Shall carry out an **internal risk analysis**
- Draw up **technical documentation** containing at least a general description of the product and its essential characteristics relevant for assessing its safety containing also:
 - **analysis of the possible risks** related to the product and the solutions adopted to eliminate or mitigate such risks, including the outcome of any reports related to tests conducted by the manufacturer or by another party on their behalf
 - include the **reference of relevant European standards** or other elements that have been used to assess the safety of the product
- The technical documentation shall be kept for a period of 10 years.
- Product documentation available to authorities upon request.
- Products produced in series: shall ensure that procedures are in place to remain in conformity.
- **Marking Requirements** (easily visible and legible to consumers):
 - Include the product type, batch or serial number, or any other element that allows for clear identification of the product.
 - Provide the manufacturer's name, registered trade name, or trademark.
 - Display the postal and **electronic address** of the manufacturer, along with the contact details for a single point of contact if different.
- Additionally, clear **instructions and safety information** must be provided in a language easily understood by consumers—if necessary for the correct and safe use of the product.

Obligations of Manufacturers, *Article 9*

In Case of Dangerous Products



- Manufacturers must immediately:
 - Implement appropriate corrective actions
 - Notify consumers and all relevant economic operators (art 35, art 36)
 - Inform market surveillance authorities via the Safety Business Gateway
- Manufacturers must provide publicly accessible communication channels – such as a phone number, email address, or a dedicated section on their website – for submitting complaints or reporting accidents or safety concerns.
- Manufacturers must maintain an internal register documenting:
 - Received complaints
 - Investigations carried out
 - Product recalls
 - Corrective measures taken to ensure compliance
 - Personal data included in this register must not be retained for more than five years.

Obligations of Importer, *Article 11*



- Importers shall indicate **their name, their registered trade name or registered trademark, their postal and electronic address** and, where different, the postal or electronic address of the single contact point at which they can be contacted.
- This information should be **affixed directly to the product**. If that is not feasible, it may be placed on the packaging or in an accompanying document.
- Importers shall ensure that any additional label does not obscure any information required by Union law on the label provided by the manufacturer.
- Ensure that the imported product includes **clear instructions and safety information** in a language easily understood by consumers—where necessary for correct and safe use.
- Guarantee that storage and transport conditions under their responsibility, do not compromise the product's compliance with general safety requirements.
- **Retain a copy of the manufacturer's technical documentation and keep it for a period of 10 years.**

Obligations of Importer, *Article 11*

In Case of Dangerous Products

- Importer must immediately:
 - Inform the manufacturer thereof;
 - Implement appropriate corrective actions
 - Notify consumers and all relevant economic operators (art 35, art 36)
 - Inform market surveillance authorities via the Safety Business Gateway
- Importer must ensure that communication channels for submitting complaints or reporting accidents and safety issues are publicly accessible. If the manufacturer has not provided these, the importer must establish them.
- Importer must investigate all received complaints and accident reports, and ensure they are recorded either in the manufacturer's register or in the importer's own internal register
- Importers must keep the manufacturer, distributors, and, where applicable, fulfilment service providers and online marketplace operators informed promptly about the investigations conducted and their outcomes.

Obligations of Distributor, *Article 12*



- Before placing a product on the market, distributor must ensure that the manufacturer - and, where relevant, the importer- have fulfilled all applicable requirements.
- Distributors shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its conformity.

In Case of Dangerous Products

- Immediately inform the manufacturer or the importer
- Ensure that the corrective measures are taken, including withdrawal or recall
- Ensure that the market surveillance authorities are immediately informed thereof through the Safety Business Gateway.

Obligations of Providers of online marketplaces



Article 22

- Providers of online marketplaces shall **designate a single point of contact allowing for direct communication, by electronic means**, with Member States' market surveillance authorities in relation to product safety issues
- Providers shall **register with the Safety Gate Portal** and shall indicate on the Safety Gate Portal the information concerning their single contact point.
- Providers shall designate **a single point of contact to enable consumers to communicate** directly
- Providers shall ensure that they have **internal processes for product safety in place**
- Providers must display **obligatory product information in the online interface**

In Case of Dangerous Products

- Providers of online marketplaces shall cooperate with the market surveillance authorities, with traders and with relevant economic operators

GPSR

DOCUMENTATION

Assessing the safety of products, *Article 6*

Following aspects shall be taken into account:

- Product features, such as design, materials, technical specifications, packaging, and instructions for assembly, use, and maintenance.
- Interaction with other products, especially if it's likely to be used together with other items.
- Influence of external products, including accessories or add-ons that may affect how the product functions or its safety.
- Presentation and labelling, including warnings, age suitability, and safety instructions.
- Intended users, especially risks to vulnerable groups like children, the elderly, or people with disabilities - and considering gender-related health and safety impacts.
- Product appearance, particularly if it:
 - Looks like food and might be mistaken for it, especially by children.
 - Resembles a toy or child-friendly object, even if not intended for children.
- Cybersecurity, if relevant, to protect the product from external threats that could impact safety.
- Smart features, like learning or predictive functions, if applicable.

Risk Assessment

Following aspects shall be taken into account:

- The content of a risk assessment will vary depending on the product's complexity and the level of potential hazards involved.
- Typical hazards to consider - depending on the nature of the product - include:
 - Physical
 - Mechanical
 - Flammability
 - Electrical
 - Chemical, and more
- **There is no standard, universally required template for conducting a risk assessment.** However, various guidance documents and tools are available to support its development.

Technical Documentation

Mandatory



- **The presence of a technical documentation for each item is a legal requirement.**
- **This documentation is important as a part of the evidence, demonstrating that the product meets the relevant guidelines.**
- TD is a set of documents that explains key details about a product, including:
 - A description of the product and how it is intended to be used
 - Traceability information
 - Details about design, materials, and technical features
 - Results of any safety tests or risk assessments
 - Information about how the product meets safety requirements, including test reports
 - References to standards or rules that were followed
- This documentation must be kept, usually for 10 years, and shown to authorities if requested.

Labelling and Safety information

Mandatory



All product must bear label with:

- Product ID
- Batch number
- Manufacturer / Importer name, registered trade name or registered trademark
- Postal and electronic address

Label should be present on the product.

If this is not technically feasible, it may be placed on the product packaging or on an accompanying document (Instruction Manual)

Instruction Manual

- Manual is applicable for each product which needs additional instruction or information.
- Clear usage instructions, safety information and warnings, must be provided in a language easily understood by consumers.

GPSR

SAFETY GATE

Safety Gate Rapid Alert System

Formerly RAPEX



- [Safety Gate portal](#) (formerly known as RAPEX) is the European system for reporting dangerous products between the Member States and the European Commission.
- In the Safety Gate system, Member States and the European Commission can quickly exchange information about non-food products, that pose a serious risk to the health and safety of consumers.
- The product may then be withdrawn from the market or safety warnings may be issued.
- Every day, national authorities post warnings on Safety Gate. These warnings contain information about the type of product that has proven to be dangerous, a description of the risk and the measures taken by the company concerned.
- The other authorities take measures themselves in response to the warnings if they find the product on their own market.
- Stay up to date with [Safety alerts](#).

GPSR

FAQ

FAQ

Electronic address

Whose name and address must be on products?

- Under the General Product Safety Regulation (GPSR), only
 - **the manufacturer,**
 - **importer, and**
 - **EU responsible person**are explicitly required to include their
 - **name,**
 - **postal address, and**
 - **electronic address on the product or its packaging.**
- However, if an authorised representative has been given a written mandate by the manufacturer to act as the responsible person under the GPSR, they must fulfil the obligations associated with that role.
In such cases, their contact details must also be clearly indicated on the product or its packaging, as specified in Article 16(3).



FAQ

Electronic address

Electronic address - What does it mean?

- Electronic address is a communication channel, enabling consumers to reach the company directly, such as:
 - **Telephone number,**
 - **E-mail address,**
 - **or dedicated section of the website**



FAQ

Electronic address

Disclosing information on products?

- While the new regulations requiring disclosure of manufacturer information may initially cause concern, they are unlikely to present a significant challenge for most retailers.
- On the contrary, these rules offer an opportunity to **enhance transparency and build trust** with consumers.
- Rather than viewing them as a threat to competitive advantage, retailers should prioritize accurate product labelling and leverage the regulations to reinforce their credibility and position in the e-commerce market.



FAQ

Unsafe product on the market

What are possible consequences if a product is unsafe?

- **Severe injuries** to children or other intended users, along with potential legal repercussions
- Mandatory **product recalls**
- **Listing in** the Rapid Information Exchange System (**Safety Gate**, formerly RAPEX) by authorities
- **Fines and sanctions**, defined by each Member State under the GPSR for non-compliant economic operators
- **Damage to brand reputation**
- **Lost consumer trust**



Thank you!

