



Product Compliance & GPSR

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01

General product safety Regulation (EU) 2023/988

Backgrounds

Reasons for the need of a new General product safety regulation:

- The old Directive 2001/95/EC needs to be revised and updated in light of the developments related to new technologies and online selling, to ensure consistency with developments and to ensure a better functioning of product safety recalls. (Preamble, Recital 2)
- Despite the development of sector-specific Union harmonisation legislation, it is practically impossible to adopt Union law for all consumer products. There is therefore a need for a broad-based legislative framework of a horizontal nature to fill gaps and to complement provisions in Union harmonisation legislation and ensure consumer protection. (Preamble, Recital 6)

Goal

The aim of this Regulation is to ensure the health and safety of consumers and the functioning of the internal market as regards products intended for consumers.

(Preamble, Recital 4)

Consumers should have at their disposal sufficient means to enforce that right and Member States should have adequate instruments and measures at their disposal to enforce this Regulation.

(Preamble, Recital 5)



Validity

The GPS Regulation entered into force on 12.06.2023 and will apply from 13.12.2024. The predecessor legislation 2001/95/EC will be repealed on the same day. (Art. 50/52)

It applies directly to all products for which there are no specific safety regulations in all EU states. (Art. 2)

But:

- If there are specific safety requirements, this Regulation shall apply to the aspects and risks not covered by them.
- The safety requirements of the GPSR do not apply to products that fall under safety-relevant EU harmonisation legislation (e.g. 2014/35/EU).

The GPSR applies to products placed on the market or made available on the market. (Art. 2) This includes products that are

- new, used, repaired or refurbished and
- offered for sale online or via another form of distance selling (Art. 4)
- not food



Products that fall under safety-relevant EU harmonisation legislation

- Medical Devices
- Cosmetic Products
- Toys
- Electrical and electronic equipment
- Machines
- ...

Following requirements apply to these products in the GPSR:

- Chapter I (General Provisions)
- Chapter II (Safety Requirements / Art. 5 to 8)
- Chapter III Section 2 (Obligations of economic operators)
- Chapter IV (Providers of Online Marketplaces)
- Chapter VI (Safety Gate)
- Chapter VIII (Right to information and to a remedy)

02

Roles & Obligations

Who does the regulation apply to?

In principle, the following applies:

A product shall not be placed on the market unless there is a responsible economic operator! (Art. 16)

And:

Economic operators shall place or make available on the market only safe products. (Art. 5)

General Responsibility

Internal processes for product safety (Art. 14):

“Economic operators shall ensure that they have internal processes for product safety in place, allowing them to comply with the relevant requirements of this Regulation”

Cooperation of economic operators with market surveillance authorities (Art. 15):

On request by a market surveillance authority, the economic operator shall provide all necessary information, in particular:

- (a) a full description of the risk presented by the product, related complaints and known accidents; and
- (b) a description of any corrective measure taken to address the risk.

Economic operators shall be able to present the information for a period of 10 years after they have been supplied with the product or after they have supplied the product, as applicable.

Every economic player must be aware of their role:

(EU) 2023/988 (new)	2001/95/EC (old)	Material obligations*
Manufacturer	Manufacturer	Ensures that the product meets the safety requirements, is correctly labelled and has sufficient technical documentation (Art. 9) + risk analysis + labelling with an „electronic address“
Importer	Representative of the manufacturer, importer	Ensures that the manufacturer fulfils his obligations. (Art. 11)
Fulfilment service provider	-	As an economic operator, may only place safe products on the market. (Art. 5)
Authorised representative	-	Maintains the technical documentation and co-operates with the market surveillance authorities. (Art. 10)
Distributor	Distributor	Ensures that the manufacturer and, where applicable, the importer have fulfilled their obligations. (Art. 12)
Provider of an online marketplace	-	Provides the necessary product information and co-operates with the market surveillance authorities (Art. 22)

*: The complete obligations can be found in the respective article

Obligations of Manufacturers

When placing their products on the market, manufacturers shall ensure that those products have been designed and manufactured in accordance with the general safety requirement (Art. 5)

Before placing their products on the market, manufacturers shall carry out

- An internal risk analysis
- Preparation of technical documentation (general description of the product & essential characteristics relevant for assessing its safety)

Additionally, the manufacturers

- Ensure that the product is compliant with all relevant legislations
- Keep documentation available for 10 years after the product has been placed on the market
- Ensure that their products bear a type, batch or serial number enabling the identification
- Attach the required product labelling to the product (see slide 45)
- Add clear instructions and safety information in the official language of the member state
- shall investigate complaints submitted, information received on accidents, and shall keep an internal register of those complaints as well as of product recalls and corrective measures.

Obligations of Importers

- Ensure product compliance **Before** making a product available on the market
- Where an importer has reason to believe that a product is not in conformity, the importer shall not place the product on the market until the product has been brought into conformity and
 - Inform the manufacturer / consumer
 - Inform the market surveillance authorities through the Safety Business Gateway
- Indicate their name, their registered trade name or registered trade mark, their postal and electronic address and, where different, the postal or electronic address of the single contact point at which they can be contacted.
- Ensure that the product has clear instructions and safety information in the official language of the member state
- Ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its conformity with the general safety requirements.
- Keep documentation available for 10 years after the product has been placed on the market

03

Product Safety & Risk Assessment

When is a product safe?

Assessment of the safety of the product (Art. 6) based on the

- Properties, design, technical characteristics, composition, product packaging, installation and usage instructions, use and maintenance,
- Effect on other products,
- Presentation, labelling, age labelling, safety instructions,
- Consumer categories that are used,
- appearance, e.g. in connection with replicas of foodstuffs or protective equipment,
- inadequate cyber security,
- developing, learning and predictive functions

Mandatory risk analysis to assess product safety

NEW:

According to Art. 9, the manufacturer is obliged to carry out a risk analysis. The following requirements can be derived from recital / consideration (33):

1. the technical documentation and its scope must result from the risk analysis.
2. It should include a description of the product and the elements necessary to assess the risks.
3. In the case of complex products or products that present potential risks, risks must be analysed and the technical means of minimising these risks must be described.
4. If standards are used, a list of these standards should be provided.

The General product safety Regulation does not specify a formal requirement for the form of the risk analysis. However, the following is recommended as a template

- EN 12100, this standard is harmonised for machinery,
- the Cenelec Guide 32, a guide to the risk assessment of electrical appliances.

Tools for assessing product risks

If a product fulfils technical safety standards, then

- the product is considered safe if it complies with harmonised standards. In this case, the presumption of conformity applies to the scope of the standard. (Art. 7)
- there is a low safety risk from the product if it complies, for example with
 - other recognised standards,
 - Recommendations or guidelines of the EU Commission,
 - suitable certification systems,
 - the current state of the art

(Art. 8)

04

Labelling

How must a product be labelled?

(after General product safety

Regulation (EU) 2023/988)

Contents	Product (type plate)	Packaging/instructions/accompanying documentation	New: Distance selling information carrier*
Name or brand of the manufacturer, postal address, Electronic address at which he can be contacted	X	If not possible on the product	X
If manufacturer is not in the EU: Name or trade mark of the person responsible, postal address, electronic address at which he can be contacted,	X	If not possible on the product	X
Information that enables the product to be identified, including an image of the product	X	If not possible on the product	X
any warnings or safety information	X	If not possible on the product	X
Sources:		Art. 9	Art. 19

*: e.g. online sales website, display at the point of sale, etc.

Product labeling



Bereich	Gesetzgebung
Safety of electrical appliances, EMC+Radio Ecodesign	<ul style="list-style-type: none">• CE mark• Name and address of the manufacturer and importer• Produktname, -bezeichnung und -nummer/ID• Standard-specific safety data (voltage, current, AC - primary & secondary, outdoor symbol, IP specification)• Warnings
Energy labeling	<ul style="list-style-type: none">• E-Label
WEEE	<ul style="list-style-type: none">• Waste garbage can symbol (with underline)

Product labeling

- Luminaire



- Li-ion battery



- Button cell



05

EU-Authorised Representative



EU Authorised Representative

The European Authorized Representative is necessary for companies,

1. which are **not located in the EU** (UK, US, China etc.)

AND

2. are selling directly to **end users in the EU** (e.g. via online-shop, online platforms etc.)

With our service we fulfill the requirements as **EU responsible person** for:

- **German product safety act (ProdSG)**
- **EU-Regulation on Market Surveillance (Regulation (EU) 2019/1020)**
- **EU General Product Safety Regulation (GPSR)**

EU Authorised Representative

Duties of the Authorized Representative
(Regulation (EU) 2019/1020 / ProdSG)

The Authorized Representative takes over some of your duties from the Market Surveillance Regulation (Art. 4 Regulation (EU) 2019/1020)



Stores declaration of conformity and technical documents



Contact person for market surveillance authorities



Cooperation with authorities



Product sampling on the market



Keeps track of product safety complaints

06

Summary and Offer

Summary

- The new Product Safety Regulation (GPSR) (EU) 2023/988 will apply directly in the EU member states from 13th December 2024.
- It is harmonised with the market surveillance regulation (EU) 2019/1020 and has many features of the CE directives, such as the preparation of a risk analysis. However, a DoC is not required.
- Obligations of economic operators in distance selling are included as well.
- A risk analysis is mandatory.
- The product labelling information has essentially been expanded to include an e-mail contact address.
- Recall management for unsafe products on the market has been tightened up.
- Sellers out of the EU selling directly to EU-customers need an EU Authorized Representative

Who is e-systems?



take way

Consultancy company and service provider for **product responsibility under waste legislation:**

- Electrical equipment
- Batteries
- Packaging
- Trade redemption

get right

Position of the **authorised representative** for:

- Electrical equipment
- Batteries
- Packaging
- Product safety
- and EPREL

trade bility

Consultants & service providers to ensure **marketability:**

- Product Compliance (non-food area)
- Product labelling
- Product certification (*cert-e-fied*)

- **Internationally** active corporate group based in **Hamburg**
- Experience since **2005**
- More than 130 employees support more than **7,000** manufacturers
- Consultancy in the most important **European** languages and **Chinese**

**Thank
you!**

**Contact
us!**

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