European Commission

SafetyGate

Guidelines on the application of the EU general product safety legislative framework by businesses

1. Introduction

As of 13 December 2024, the new **General Product Safety Regulation, Regulation (EU) 2023/988 (the GPSR)**[(1)] sets a new general framework for the safety of consumer non-food products in the EU. It also repealed the previous General Product Safety Directive (Directive 2001/95/EC)[(2)].

These guidelines, required under the Article 17(2) of the GPSR, aim to help businesses and particularly small and medium-sized enterprises (SMEs), including micro-enterprises, to better understand and fulfil their obligations under this new Regulation. To ensure this objective, when preparing these guidelines, the Commission consulted representatives of SMEs and micro-enterprises in the context of the GPSR SMEs Sounding Board and also reflected questions raised by stakeholders on the GPSR interpretation during the first year of its implementation.

The main objective of the GPSR is to ensure that only safe products are placed or made available on the EU market. It is important to protect EU consumers against dangerous products, and to ensure a level-playing field for businesses.

The GPSR establishes the general safety requirement that **economic operators should place or make available only safe products on the EU market**. The GPSR establishes a coherent set of minimum product safety requirements that businesses need to comply with in order to ensure that only safe products are circulating on the EU market. It applies to products insofar as there are no specific provisions with the same objective under Union law that regulate the safety of the products concerned or a risk associated to such product.

National market surveillance authorities enforce the obligations laid down by the GPSR. They check that products on the EU market are safe and that businesses comply with their obligations. If a dangerous product is detected, Member States inform each other via the EU Safety Gate Rapid Alert System, which is managed by the European Commission; the public is informed via the Safety Gate Portal[(3)].

Member States may also fine businesses that breach their obligations under the GPSR.

(1) Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (OJ L 135, 23.5.2023, p.1).

(2) Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4–17).

(3) Safety Gate Portal Website: https://ec.europa.eu/safety-gate/#/screen/home.

DG Justice and Consumers

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These guidelines are intended purely as a guidance document – only the text of the EU legislation itself has legal force. Any authoritative reading of the law has to be derived from the text of the GPSR or other relevant Union legislation. The binding interpretation of EU legislation is the exclusive competence of the Court of the European Union. The views expressed in this Guide cannot prejudge the position that the Commission might take before the Court of Justice.

The information in these guidelines is of a general nature only and does not specifically address any particular individual or entity.

Neither the European Commission nor any person acting on behalf of the European Commission is responsible for any use that may be made of the following information. These guidelines reflect the situation at the time of drafting. The guidance offered may therefore be modified at a later date.

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1.1 Which businesses are subject to obligations under the GPSR?

All businesses involved in the supply chain have a role to play in ensuring product safety and therefore have corresponding obligations to fulfil.

The obligations of the GPSR are relevant for all sizes of business [(4)].

In general, the GPSR differentiates between two main categories of businesses:

A. **Economic operators**: 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 manufacturing of products or making products available on the market in accordance with the GPSR.

- The manufacturer is any natural or legal person who manufactures a product or who has a product designed or manufactured, and markets that product under that person's name or trademark;
- The authorised representative is any natural or legal person established within the EU 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 the GPSR;
- The importer is any natural or legal person established within the EU who places a product from a third country on the EU market;
- The distributor is any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;
- The fulfilment service provider is any natural or legal person who offers at least two of the following services in the course of a commercial activity: warehousing, packaging, addressing or dispatching, without having ownership of the products involved, excluding postal services as defined in Article 2 point (1) of Directive 97/67/EC of the European Parliament and of the Council, parcel delivery services as defined in Article 2 point (2) of Regulation (EU) 2018/644 of the European Parliament and of the Council, and any other postal services or freight transport services;
- The responsible person for products placed on the EU market ('responsible person') is an economic operator established in the EU who is responsible for the tasks set out in Article 4(3) of the Market Surveillance Regulation (Regulation (EU) 2019/1020) and in the GPSR (see point 3.2 for details on these tasks).

B. **Providers of online marketplaces**

Providers of online marketplaces provide intermediary services for offers of third-party traders and consumers (business-to-consumers), using an online interface, as generally established under Regulation (EU) 2022/2065 (the Digital Services Act –'DSA').

Under the GPSR, the term '**trader**' means any natural person or any legal person who is acting, including through any person acting in that natural or legal person's name, for purposes relating to trade, business, craft or profession.

Purely consumer-to-consumer transactions do not fall under the scope of the GPSR.

Your company can fall into more than one category of business, depending on the service it provides for different products. *The service you offer for a given product determines whether you act as an economic operator or as a provider of an online marketplace.*

Example 1: *A company that resells products can be both (i) a distributor for the products it has purchased from a manufacturer and resells on the market; and (ii) a manufacturer for products it has rebranded and sells under its own name.*

Example 2: *A provider of an online marketplace can be considered as (i) a provider of an online marketplace for products for which it provides only an intermediary service(s); (ii) as a fulfilment service provider for products for which it provides fulfilment service, and (iii) as a manufacturer for products sold under its own name.*

[(4)] With the exception of certain obligations of providers of online marketplaces as explained in point 3.3 of this guidance.

Learn what responsibilities relating to product safety and established by the GPSR you have in the relevant sections of these guidelines.

These guidelines explain to you what your obligations under the GPSR are.

These obligations have been applicable since **13 December 2024 and concern all products on the EU market that fall within the scope of the GPSR, (regardless of their place of production)**.

Member States must not prevent the making available on the market of products covered by the previous General Product Safety Directive [5] that are in conformity with that Directive and were placed on the market before 13 December 2024.

The GPSR covers a wide variety of products and therefore does not establish specific obligations by sector. For products covered by specific EU sectoral rules, the GPSR complements these sectoral rules (as explained in more detail in point 2.2 of these guidelines).

Remember that providing safe products to consumers is not only a legal requirement but also increases trust in your company.

1.2 What is a safe product?

The GPSR requires that only **safe** products be placed on the market. This is what we call the **general safety requirement**.

A product is considered safe if, under normal or reasonably foreseeable conditions of use, including the actual duration of use, it either does not present any risk or only presents the acceptable minimum risks compatible with the product's use, thereby being consistent with a high level of protection of the health and safety of consumers.

In line with the definition of health established by the World Health Organization, this definition also includes risks to **mental health**. For example, the design and the foreseen use of your product should not create risks for consumers' cognitive abilities or cause depression, anxiety or poor sleep quality.

Any environmental risk must also be taken into account, insofar as it entails a risk to the health and safety of consumers.

In order to meet the general safety requirement, the product must therefore be subject to an assessment of **the potential risks** that it can pose to the health and safety of consumers (a risk assessment), taking all relevant aspects of the product into consideration, and be designed to address those risks.

A product is presumed to be safe if it complies, for each of the safety risks it may pose, with the relevant applicable European standards the reference to which have been published in the Official Journal of the EU [6] or, in the absence of such standards, with national health and safety requirements contained in the law of the Member State in which it is made available. In other words, such products will benefit from a **presumption of conformity** with the general safety requirement [7].

What are European standards and how can you use them?

In some areas and for certain products, the European Commission requests one of the official standardisation organisations, (CEN, CENELEC and ETSI), to develop standards which embody and transform the general safety requirement contained in the GPSR into technical norms. The references to these standards are published in the Official Journal of the EU. These standards grant a **presumption of conformity** with this general safety requirement to products that were developed according to these standards for the **risks covered by these standards**. A list of the standards supporting the GPSR is updated regularly and is publicly available [8]. European standards, the references of which have been published in accordance with Directive 2001/95/EC,

[5] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4).

[6] See, e.g., Commission Implementing Decision (EU) 2019/1698 of 9 October 2019 on European standards for products drafted in support of Directive 2001/95/EC of the European Parliament and of the Council on general product safety (OJ L 259, 10.10.2019, p. 65–74).

[7] It is important to note that the presumption of conformity with the general safety requirement described here shall not prevent market surveillance authorities from taking all appropriate measures under the GPSR where there is evidence that, despite such presumption, the product is dangerous (cf. Article 7(3) GPSR).

[8] The list can be found in Commission Implementing Decision (EU) 2019/1698 of 9 October 2019 on European standards for products drafted in support of Directive 2001/95/EC of the European Parliament and of the Council on general product safety (OJ L 259, 10.10.2019, p. 65–74).

continue providing a presumption of conformity with the general safety requirement laid down in the GPSR. These European standards can be found in the **catalogue of national standardisation organisations**.

Although these standards are **not legally binding**, economic operators are encouraged to use these standards when they exist. This is because compliance with these standards provides a **straightforward way** for economic operators to fulfil their **obligation to place only safe products on the EU market**. European standards indeed clearly set out the technical requirements and testing methods that help to ensure the safety of products.

Since technical standards are not mandatory, manufacturers can always use other internal methods to demonstrate the safety of their products. However, those products will not benefit from a presumption of conformity with the general safety requirement, and it will be the manufacturer's responsibility to precisely show how the identified safety risks have been tackled (eliminated or mitigated). Using European standards thus makes compliance easier for businesses regarding the aspects covered by those standards.

It can also happen that there is no standard for a given product. Economic operators should then turn to other means to ensure and demonstrate that their products are safe. More practical information can be found on this in section 3.1.1.

What does the precautionary principle entail for you?

The **precautionary principle** requires that precautionary measures are taken when there is reason to doubt the safety of a product's impact on human health.

A reference to the precautionary principle figures prominently in Chapter I of the GPSR, highlighting that all actors who are subject to the obligations of the GPSR must take due account of the precautionary principle when implementing these obligations.

This means that all businesses (economic operators or providers of online marketplaces) must take due account of the precautionary principle when fulfilling their relevant obligations under the GPSR.

> ***Example:*** *if you are a manufacturer, you should take due account of the precautionary principle when carrying out your internal risk analysis and drawing up the technical documentation about your product, or when you need to take corrective measures or to report any indication that your product is dangerous. Already taking the precautionary principle into account during the design stage allows you to ensure that your products are safe by design.*

In short, **the precautionary principle requires all economic operators to proactively prevent hazards to human health**, and to foresee, as far as possible, what dangers a product can pose.

2. What is the scope of the GPSR?

2.1 What types of products and sale channels are covered by the GPSR?

The GPSR covers consumer products.

Nevertheless, products which were initially designed exclusively for professional use, but have subsequently migrated to the consumer market, should also be subject to the GPSR because they could pose risks to the health and safety of consumers when used in reasonably foreseeable conditions. An example would be typical renovation and construction products sold in DIY (Do-It-Yourself) shops that sell directly to ordinary consumers.

The GPSR **product definition is wide enough to cover "any item"**, whether tangible or non-tangible or of a mixed nature. It **includes apps and software products**, including for example chatbots, and sets requirements for their safety. This definition also allows the GPSR framework to be used for products that might appear on EU consumer markets in the future.

The GPSR applies to products placed or made available on the m**arket whether** new, used, repaired or reconditioned. The GPSR obligations therefore apply fully to second-hand, refurbished and reconditioned products, including repaired products when placed or made available on the market by an economic operator (but not self-repairs done by consumers). It does not apply to products that have to be repaired or reconditioned prior to being used if those products are placed or made available on the market and are clearly marked as such.

The obligations of the GPSR apply to products **placed or made available on the market as of 13 December 2024,** and to **any offer of products made on that date or later**. Against this context, products covered by the previous General Product Safety Directive that are in conformity with that Directive and were placed on the market before 13 December 2024 can be made available on the market also after 13 December 2024.

This means that, for example, the new requirements to affix certain traceability and product safety information to the product, or its packaging, under the GPSR do not apply to products that were placed on the market before 13 December 2024.

Please remember that placing on the market means the very first making available of the product on the Union market. This needs to be determined at the level of every specific unit of the product.

Sales channels covered

The GPSR ensures that consumers have access to safe products whichever the sales channel they choose. **The GPSR therefore covers product safety for all types of sales channels, including online sales and other types of distance sales**. The GPSR also ensures that consumers have access to the same product and safety information when buying a product online or through other types of distance sales, just as they would have in a bricks-and-mortar shop.

Products offered for sale online or through other means of distance sales are considered to be made available on the market if the offer is targeted at consumers in the EU. An offer for sale is considered, after a case-by-case analysis, to be targeted at consumers in the EU, if the relevant economic operator directs its activities to one or more Member States. Relevant factors that should be taken into consideration for the case-by-case analysis include [(9)]:

- the geographical areas to which dispatch is possible,
- the languages available, used for the offer or for ordering,
- the means of payment and,
- the use of the currency of the Member State or a domain name registered in one of the Member States.

[(9)] See also Recital 21 of the GPSR.

2.2 Link to EU harmonisation legislation and other EU legislation

The GPSR complements **EU harmonisation legislation** [10] and thus provides a safety net for all products placed or made available on EU markets.

- The GPSR applies to products that are placed or made available on the market insofar as there are no specific provisions with the same objective under EU law which regulate the safety of the products concerned.
- Where products are subject to specific safety requirements imposed by EU law, the GPSR applies only to those aspects, risks, or categories of risks, which are not covered by those requirements.

Example: *For example, the GPSR applies fully to, inter alia, childcare articles, gymnastic equipment and furniture, since these categories of products are not subject to specific requirements imposed by other EU legislation. In the case of low voltage devices, the GPSR would still apply for some new technology-related aspects, such as self-learning capabilities, if these are not covered by the EU Low Voltage Directive (LVD)* [11]*. Similarly, the GPSR will cover the safety risks of low-risk Artificial Intelligence (AI) products. In addition, the GPSR obligations for the providers of online marketplaces also apply to products subject to specific safety requirements under other EU legislation.*

With regard to **products already subject to specific requirements imposed by EU harmonisation legislation**:

The following Chapters **are applicable** subject to the conditions listed above:

- ✓ **Chapter I** – general provisions;
- ✓ **Chapter II** – safety requirements: this chapter applies only to the risks or categories of risks not covered by EU harmonisation legislation
- ✓ **Chapter III Section 2** – economic operator obligations regarding distance sales, reporting on accidents related to products, and the provisions on information in electronic format;
- ✓ **Chapter IV** – providers of online marketplaces;
- ✓ **Chapter VI** – the Safety Gate Rapid Alert System and Safety Business Gateway;
- ✓ **Chapter VIII** – right to information and to a remedy.

The following chapters **do not apply**:

- ✓ **Chapter III, Section 1** (the part of the obligations for economic operators not mentioned in the paragraph above);
- ✓ **Chapter V** (Market surveillance and implementation);
- ✓ C**hapter VII** (Commission's role and enforcement coordination); and
- ✓ **Chapters IX to XI** (International cooperation, Financial provisions, Final provisions).

The GPSR is interlinked with the Market Surveillance Regulation [12] in the sense that several of the provisions of that Regulation, notably those concerning the powers of market surveillance authorities, also apply to surveillance of products covered by the GPSR [13]. In addition, the GPSR naturally also has **strong interlinks with other relevant EU legislation** concerning illegal content online, including the Digital Services Act [14].

[10] Union legislation listed in Annex I to 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 (OJ L 169, 25.6.2019, p. 1–44), and any other Union legislation harmonising the conditions for the marketing of products to which that Regulation applies.

[11] Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (recast) (OJ L 96, 29.3.2014, p. 357–374).

[12] 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 (OJ L 169, 25.6.2019, p. 1–44).

[13] See Article 23 GPSR.

[14] Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act) (OJ L 277, 27.10.2022, p. 1–102).

2.3 What kind of products are excluded from the scope of the GPSR?

The following **products and product groups are excluded** from the scope of application of the GPSR:

a) medicinal products for human or veterinary use;

b) food;

c) feed;

d) living plants and animals, genetically modified organisms and genetically modified microorganisms in contained use, as well as products of plants and animals relating directly to their future reproduction;

e) animal by-products and derived products;

f) plant protection products;

g) equipment on which consumers ride or travel if that equipment is directly operated by a service provider within the context of a transport service provided to consumers and is not operated by the consumers themselves;

h) aircraft referred to in Article 2(3) (d) of Regulation (EU) 2018/1139; and

i) antiques (i.e. products, such as collectors' items or works of art, in relation to which consumers cannot reasonably expect that they fulfil state-of-the-art safety standards).

Moreover, the GPSR does not apply to **products to be repaired or to be reconditioned before use** if those products are placed or made available on the market and are clearly marked as such. It would nevertheless apply to second hand products, repaired, refurbished or reconditioned products placed or made available on the market as such.

Services are not covered by the GPSR but **products provided to consumers in the context of a service** are covered by the GPSR. For example:

- Products supplied to consumers that are used outside the premises of a service provider, (e.g., bikes rented);
- Products used in the premises of a service provider, if consumers themselves actively operate a product, (e.g., fitness machines in fitness centres);
- Products directly used by consumers during the service provided, and this even if such use is passive (e.g., those products are being applied to the consumers by the service providers such as cosmetics products used in cosmetic saloons or tattoo inks used in tattoo salons).

3. My responsibilities

To understand what your responsibilities under the GPSR are, you must first determine what role you are playing for the products you handle.

Under new and emerging complex business models, the same business entity can provide a variety of services.

Depending on the nature of the services you are providing for a given product, you may fall under one or more of the following categories of businesses under the GPSR for that particular product [(15)]:

- if, you as a business, **only provide online intermediation services** for a given product, (e.g., by allowing third party offers to be listed on your interface), then for the sale of that specific product you qualify as **a provider of an online marketplace** and must therefore comply with the requirements of Chapter IV of the GPSR and the other provisions of the GPSR that specifically address the providers of online marketplaces.
- if you also act as an economic operator for other product(s) (e.g., by offering your own branded products, acting as a distributor or importer or providing fulfilment services), here you must comply with the relevant obligations of Chapter III of the GPSR and the other provisions of the GPSR addressing economic operators, generally or specifically.

Example: *A company provides an online marketplace. If this company offers its own branded product on this online interface, it would be considered for these products as an economic operator(manufacturer), even if the company did not produce it itself.*

- if you qualify as or provide services as a responsible person (e.g., by acting as the authorised representative of a third country manufacturer or as a fulfilment service provider), you must comply with the obligations of the responsible person (see point 3.2 for more details about the responsible person).

It is strongly recommended that you carefully analyse the services you offer for the products you are handling in order to determine into which business category or categories you fall for a given product. Remember that you may fall into different business categories for different products and might thus need to comply with different sets of obligations in parallel.

The responsibilities described below are without prejudice and come on top of your obligations specified under other Union harmonisation legislation or other EU legislation.

[(15)] This does not exclude that for another product, for which you are providing different services, you fall under another business category (categories) under the GPSR. The one and same business can fall under several business categories, depending on the role(s) it plays with respect to each of the products it handles.

3.1 Economic operators

3.1.1. I am a manufacturer: what are my obligations under the GPSR?

Who is a manufacturer?

The GPSR defines a manufacturer as any natural or legal person who manufactures a product or has a product designed or manufactured, and who markets the product under the person's name or trademark.

Firstly, the manufacturer must first have either manufactured the product, or had a product designed or manufactured on its behalf. Secondly, it must market the product under its name or trademark.

Natural or legal persons are therefore considered manufacturers if they market the product under their name (even if they did not produce the product themselves); additionally, they are also considered manufacturers if they substantially modify the product manufactured by another person and place it themselves on the market.

Example: *A company A purchases mugs from another company B that produced them. Company A brands them with its logo and sells to consumers. Company A becomes the manufacturer of these mugs and is subject to the manufacturer's obligations under the GPSR.*

As a manufacturer, you play the most important role to play in product safety since you are involved from the design stage of the product onward.

Your overall obligation is to ensure that the products you place on the market have been designed and manufactured in such a way that they are safe.

How to design safe products? The importance of the internal risk analysis

You have an obligation to only place or make available products that are safe by design. For this purpose, you must carry out an **internal risk analysis**, which means a proper **risk assessment of the product**.

You have to take into account a number of **elements when assessing the safety of a product**. The GPSR provides a non-exhaustive list of elements that need to be taken into account when analysing the potential risk of a given product.

You must first consider the **characteristics** of the product. These include its design, technical features, composition, packaging and instructions.

If your product may be used with other products, you also need to take into account the **effect of your product** on these other products and the **effect that other products** might have on your product. For example, a software, or its update, might cause overheating of the device due to prompting the device's processor to overwork.

You will also need to consider how to **present** your product and which safety information, label, warning and instructions for its safe use and disposal you need to affix on your product or its packaging. For instance, depending on the nature of the product, you may need to label the product regarding its age suitability for children, as well as to add any appropriate warnings and instructions.

You also need to bear in mind the **categories of consumers** using your product. You have to pay particular attention to the potential risks that your products might pose for consumers in situations of vulnerability (e.g., children, older people, persons with disabilities…) and take into account characteristics such as the **gender** of the user.

Example: *: Depending on the nature of the product, you may need to consider that women are usually smaller than men, so that the product's potential risks must take into account different possible body sizes.*

Furthermore, you need to consider the **appearance** of your product, especially when it is likely to confuse consumers. This mainly concerns:

- **Food-imitating products**: you must assess if your product looks like food and can lead consumers to put it in their mouth. Examples would include decorative articles that look like fruits, or a bar of soap that looks like a cupcake, and from which small pieces could detach if bitten into.
- **Child-appealing products**: you must assess if your product, even if not intended for children, is likely to attract their attention and therefore be used by them. This could be the case for instance with a battery or a detergent decorated with cartoon characters.

Depending on the nature of your product, you will also have to take into account the **cybersecurity features** necessary to protect it against external influences and its **evolving, learning and predictive functionalities**.

As explained in the second section of these guidelines, your product will presume to be safe if it complies with (i) the relevant European standards, the references to which have been published in the Official Journal of the EU, for the risks covered by these standards or in their absence, (ii) with the relevant national requirements of the Member State in which your product will be placed or made available on the market.

However, if your product **does not benefit from such a presumption of safety**, or for the risks not covered by these standards, you should carry out a full assessment of its potential risks and ways to eliminate or mitigate them.

In this case, in order to assess the risks of your product, you will need to consider to take into consideration a number of additional elements, if available:

a) Other European standards;

b) International standards;

c) International agreements;

d) Voluntary certification schemes or similar third-party conformity assessment frameworks;

e) Commission recommendations or guidelines on product safety assessment;

f) National standards drawn up in the Member State in which the product is made available;

g) The state of the art and technology;

h) Product safety codes of good practice in force in the sector concerned;

i) Reasonable consumer expectations concerning safety; and

j) Safety requirements, adopted by the Commission via implementing acts, which are meant to be covered by European standards to ensure that the product is safe.

When do I need to draft the technical documentation? Which information should I include in the technical documentation [16]?

Before placing the product on the market, you have to carry out an internal risk analysis as mentioned above and you must draw up a technical documentation to document it [17].

The technical documentation is to be prepared with respect to each product (product model), not individual units thereof. However, if the individual units of a product (product model) are produced with different features that may impact their safety (e.g., different colour, different composition, different functionalities), that makes them specific products and specific technical documentation is required for each of them [18].

The technical documentation should contain the risk analysis of the product and highlight all the identified possible risks of the product, irrespective of their risk level.

The amount of information and the level of details to be provided in the technical documentation should be proportionate to the complexity of the product and the possible risks identified by the manufacturer.

The technical documentation should include:

- A general description of the product;
- The essential characteristics of the product that are relevant for assessing its safety (e.g., its chemical components, etc.); and

[16] See article 9(2) GPSR.

[17] Please keep in mind that Chapter III, Section I of the GPSR laying down obligations on manufacturers, including with respect to the technical documentation, does not apply with respect to products subject to specific requirements imposed by Union harmonisation legislation, as explained in Section 2.2.

[18] You do not need to keep a technical documentation of the spare parts of your product if you are not manufacturing them. If a given spare part, which you do not manufacture, influences the safety of your product, then you should take this aspect into account in your risk analysis and document it in your technical documentation.

- Where appropriate with regard to possible risks related to the product:
  - An analysis of the possible risks related to the product and the solutions adopted to eliminate or mitigate such risks (this might include the outcome of test reports);
  - A list of relevant European standards applied (if these are only partly applied, specify the parts which have been applied);
  - In the absence of relevant European standards, a list of national requirements related to the safety of the product, where available; or
  - Other elements/methods used to assess the safety/mitigate the risks of the products.

The technical documentation can be in electronic format and also in form of a file composed by different documents.

You should keep the technical documentation up to date and for 10 years after the product has been placed on the market.

Below you can find a model template that may help you in the drafting and organisation of your technical documentation. This model template is not compulsory.

Technical documentation – model template

1. Product identification:

Brand:

Name of product:

Model type/ batch / serial number or other identification element:

Product description:

Picture of product:

Packaging description:

Picture of packaging:

2. Characteristics and composition of product:

Characteristics:

Material:

Composition:

3. Risk analysis and risk mitigation measures

You have to describe separately every potential risk identified and the measures that you have taken to mitigate or eliminate this risk or the presumption of conformity provisions (e.g., use of EU standards).

Potential risk 1:

Description of potential risk:

Measures to address this potential risk:

- E.g., All substances used in the product and packaging comply with [...]
- The [...] complies with European standard [...]-
- Warnings and instructions for use provided with the product comply with European standard [...]

Potential risk 2:

Description of potential risk:

Measures to address this potential risk:

[...]

Which information should I provide on/with the product when placing a product on the market?

Information you must provide:

A. A type, batch or serial number or other element enabling its identification (e.g., barcode)

B. Your name as manufacturer

C. Your registered trade name or registered trademark

D. Your postal and electronic address and, if different, the postal address or electronic address of the single contact point through which consumers can contact you

E. Name or registered trademark, and contact details, including the postal and electronic address of the responsible person in the EU for this product

How should information listed in points A to E be displayed?

You have to ensure that consumers can easily see and read this information. It should be placed on the product or, if that is not possible, on its packaging or in a document accompanying the product. The decision where to display this information is up to you within the framework provided. You should therefore also be able to justify your choice in case of dispute. In principle, only the size

of the product (and therefore not, for example, aesthetic or similar reasons) could justify moving some required information from the product to its packaging or other accompanying documents [19].

What does "electronic address" mean?

An electronic address can be an e-mail address or dedicated section of your website that enables consumers to contact you directly and easily. A website is not in itself sufficient if it does not allow direct communication with you.

F. Clear instructions for safe use

G. Clear safety information

In which language do I have to provide the information listed in points F and G?

You must make sure that these instructions and the safety information are in a language easily understood by consumers. This is determined by the Member State on whose market you place the product.

Is this information mandatory in all cases?

No, if the product can be used safely and as you intended without such instructions and safety information, then they are not mandatory. This is the case, for instance, for products that pose risks that are well known to consumers (e.g., knives).

What are my obligations if I am located outside the EU?

It is important to underline the point that for products covered by the GPSR, you can only place a product on the EU market if there is a responsible person for it established in the EU. The responsible person of the product can be the importer, the authorised representative mandated by you or a fulfilment service provider. **The identification and contact details of the responsible person must also be indicated on the product (or on its packaging, the parcel or an accompanying document)**. This can be done directly by you or another operator, but you must ensure that your product is not placed on the EU market unless the contact details of the responsible person in the EU are provided. See more information in point 3.2.

[19] A similar approach is followed also in the guidelines of the Blue Guide on the implementation of the product rules: Commission Notice The 'Blue Guide' on the implementation of EU product rules 2022 (OJ C 247, 29.6.2022, p. 1–152).

What are my obligations if I offer a product via distance sales?

If you decide to make products available on the market online or through other means of distance sales, the offer of those products (e.g., a product offer on your e-shop) must clearly and visibly indicate at least the following information:

a. Name, registered trade name or registered trademark of the manufacturer, as well as the postal and electronic address at which they can be contacted;

b. Where the manufacturer is not established in the EU, the name, postal and electronic address of the responsible person within the meaning of Article 16(1) of this Regulation or Article 4(1) of Regulation (EU) 2019/1020;

c. Information allowing the identification of the product, including a picture of it, its type and any other product identifier; and

d. Any warning or safety information to be affixed to the product or to the packaging or included in an accompanying document in accordance with this Regulation or the applicable EU harmonisation legislation in a language which consumers can easily understand, as determined by the Member State in which the product is made available on the market.

What are my obligations if I have a registration scheme in place or a customer loyalty programme?

The GPSR sets out new obligations if you have (or plan to have):

- **a registration scheme**, through which consumers can, after purchasing a product, voluntarily communicate to the manufacturer some information such as their name, contact information, the product model or serial number, and might derive some benefit from this.
- **a customer loyalty programme** that makes it possible to identify products bought by consumers (e.g., customers have a loyalty card that is scanned when they purchase products, and the history of their purchases is available to the business that has set up the loyalty programme). This excludes customer loyalty programmes that do not enable the identification of products bought by consumers, for instance loyalty cards through which customers can receive some benefits for a

certain amount purchased, but for which no data on which products have been bought by the customer are registered.

Both systems are efficient ways to identify customers affected by a product safety recall or a safety warning. However, customers might choose not to use them because they are not interested in the other benefits offered by the registration scheme or the customer loyalty programme. They might in particular not want to be contacted for marketing purposes.

Under the GPSR, if you have a registration scheme or a customer loyalty programme in place, you must allow consumers to choose to join the registration scheme or the customer loyalty programme for safety-related purposes only.

Customers should therefore have the possibility to provide their contact details only to receive safety information (e.g., product safety recalls or safety warnings). In this case, their data should only be used to contact them in the event of a recall or safety warning and should not be processed for any other purpose (such as marketing).

After placing the product on the market:

- **Technical documentation:**
  - You should keep the technical documentation up to date. For instance, a change in the composition of the product should be reflected in the technical documentation.
  - You should keep that documentation for 10 years after the product has been placed on the market. You must be able to provide that documentation to authorities upon request.
- **Internal processes:** you should have procedures in place to ensure that products produced in series remain safe as well as internal processes for product safety in place that allow you to comply with your obligations under the GPSR (e.g., quality controls, staff trained on product safety issues and knowledgeable on EU product safety legislation, introduction of product safety learning paths, procedures to follow when information on accidents or complaint is received, etc.).

What should I do if a safety issue arises?

If you consider or have reason to believe that a product you placed on the market is dangerous (for instance because of an accident reported by a consumer or by an actor in the supply chain), you must immediately take the following steps:

1) Take the corrective measures necessary to effectively manage a safety risk and bring the product into conformity

Examples of corrective measures you can take:

- Recall of the product from end-users (see the provisions related to information on recalls, recall notices and remedies in the case of a recall in point 3.4.1);
- Withdrawal of the product from the market;
- Destruction of the product;
- Stop of sales;
- Marking the product with appropriate warnings on the risks;
- Warning consumers of the risks.

You should monitor the effectiveness of the measure you adopted and adapt it if necessary. You may have to take several different measures simultaneously.

2) Inform consumers about the dangerous product(s)

You have to inform consumers in the event of a product safety recall or a safety warning (information that has to be brought to the attention of consumers to ensure the safe use of a product. See point 3.4.1 for details).

You can use the Safety Business Gateway[20] to alert consumers and authorities at the same time (the information provided can be different in terms of details and technicality).

Information submitted via the Safety Business Gateway and intended for the public will be made available to consumers on the Safety Gate Portal.

[20] https://webgate.ec.europa.eu/safety-business-gateway/screen/public/home.

3) Inform the market surveillance authorities of the Member States in which the product has been made available on the market

How should I inform the market surveillance authorities?

You have to use the Safety Business Gateway (see point 3.4.3). This tool enables you to select all the Member States in which the dangerous product has been made available and to inform authorities immediately and simultaneously.

What type of information do I have to communicate to consumers and to authorities?

You must give details of:

- the risk to the health and safety of consumers: describe in a clear and understandable way what can happen if using the product;
- any corrective measure already taken; and
- if available, the quantity, by Member State, of products still circulating on the market.

4) Inform in a timely manner other economic operators, responsible persons, and providers of online marketplaces in the supply chain concerned of any safety issue that you have identified

This transmission of information is key to addressing the safety issue quickly.

Complaints and accidents

You have the following obligations regarding consumer complaints and accidents:

1. Have a channel for consumer complaints

You must have a communication channel such as a telephone number, electronic address or dedicated section of your website that enables consumers to submit complaints and inform you of any accident or safety issue they have experienced with a product. This communication channel might be the same as the single contact point you need to display on the product (the postal or electronic address of the single contact point at which you can be contacted).

This should take into account the accessibility needs of persons with disabilities. For instance, not all information should be in a picture that cannot be read by a text-to-audio software. [21]

2. Investigate complaints

You must investigate all complaints received from a consumer or information about an accident concerning the safety of a product. If it appears justified, you should take a corrective measure.

If the consumer has reported an accident concerning the safety of a product, you must report it to the authorities using the Safety Business Gateway.

You must keep an internal register of:

- consumer complaints and information on accidents;
- product recalls; and
- any corrective measures taken to bring the product into conformity.

You should only store in this internal register of complaints the personal data that you need in order to investigate the complaint.

Such data should only be kept for as long as they are necessary for the purposes of the investigation. In any case, you should delete personal data (e.g., the name and address of the consumer) from the register five years after the data have been entered into it.

3. Report accidents related to the safety of products

When you are informed or obtain knowledge about an accident caused by a product you placed or made available on the market, you must notify the accident to the competent authorities of the Member State where the accident has occurred, as soon as possible via the Safety Business Gateway.

When you are informed by importers or distributors that such accidents have occurred, you must notify these accidents to the competent authorities yourself or instruct the importer, or one of the distributors, to make the notification.

[21] The accessibility requirements of Annex I of Directive 2019/882 (Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the accessibility requirements for products and services (OJ L 151, 7.6.2019, p. 70–115)), are compulsory and are to be implemented in order to reflect your products' foreseeable use by persons with disabilities.

What constitutes an accident related to the safety of products?

Accidents that must be notified are occurrences associated with the use of a product that resulted in an individual's death or in serious adverse effects on that individual's health and safety. These effects can be permanent or temporary. They can include injuries, other damage to the body, illnesses and chronic health effects.

Which tool do I have to use to notify the accident?

You must use the Safety Business Gateway (see point 3.4.3).

What type of information do I have to include in the notification?

You must specify:

- the type and identification number of the product; and
- the circumstances of the accident, if known (for instance, the age of the victim of the accident if relevant, as well as how the product was being used when the accident happened).

Check list for the manufacturer

- ✓ **Safety by design**: make a proper risk assessment of the product when designing it and eliminate or mitigate all possible safety risks.
- ✓ **Think about using European standards**, the references to which have been published in the Official Journal of the EU, where they exist. They facilitate your compliance.
- ✓ **Draw up technical documentation** for your product to keep track of your internal risk assessment and keep it for 10 years.
- ✓ **Make sure you affix the necessary information to your product or its packaging**: indicate product identification details, your identification and contact details, instructions and safety information if needed.
- ✓ **Ensure that there is a responsible person for your product in the EU** and that its contact details and other required information are indicated on the product or on its packaging, the parcel or an accompanying document.
- ✓ **Display the required product information in distance sales offers**:
  - product identification details and its picture,
  - your identification and contact details,
  - identification and contact details of the responsible person for the product if you as manufacturer are not established in the EU,
  - instructions and safety information if needed.
- ✓ If you have a **registration scheme or a customer loyalty programme** in place, you must offer the possibility for consumers to subscribe for safety-related purposes only.
- ✓ Set up **internal processes for product safety**.
- ✓ **If product safety issue arises**:
  - **Take corrective measures (for recalls use the template recall notice and provide remedies)**
  - **Inform consumers**
  - **Inform national authorities via the Safety Business Gateway**
  - **Inform other businesses in the supply chain**
- ✓ Have a **direct channel for consumer complaints** about product safety and investigate these complaints: this can bring you precious information about safety of your product. Think about accessible formats.
- ✓ **Keep an internal register** of consumer complaints, product recalls and corrective measures taken.
- ✓ **Report product-related accidents** you become aware of via the **Safety Business Gateway**.
- ✓ **Cooperate with market surveillance authorities** when requested.

For more details, refer to the section 3.1.1. on manufacturer's obligations.

3.1.2. I am an authorised representative: what are my obligations under the GPSR?

Who is an authorised representative?

The GPSR defines an authorised representative as *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 the GPSR.*

An authorised representative is someone who acts on behalf of a manufacturer. The authorised representative (sometimes called an agent or agency) must have a written mandate or power of attorney from the manufacturer. ([22]) This mandate sets out the tasks to be performed by the authorised representative.

An authorised representative should not only have the formal competence to represent the manufacturer but also have the practical and administrative capacity to efficiently manage his obligations as specified in the mandate from the manufacturer, as well as his own obligations under the GPSR. An authorised representative should probably have sufficient knowledge of the language(s) necessary to communicate with the relevant market surveillance authorities, besides the necessary legal and factual knowledge.

In the mandate, the manufacturer asks you to perform at least the following main tasks to provide according to the GPSR, but a mandate may of course cover a wider range of tasks according to your general freedom of contract:

- to provide market surveillance authorities with all information and documentation necessary to demonstrate the safety of a product covered by your mandate in an official language which can be understood by the relevant authorities.
- if there is reason to believe or suspect that a product under your mandate is dangerous, to inform the manufacturer thereof;
- to notify the competent national authorities via a notification to the Safety Business Gateway (see part 3.4.3) about any action taken to eliminate risks posed by product(s) covered by the mandate, unless information about these risks has been provided by the manufacturer already; and
- to cooperate with the competent national authorities at their request on any action taken to eliminate risks posed by products covered by the mandate.

On request, you must provide market surveillance authorities with a copy of this mandate.

Internal processes: you should have internal processes for product safety in place that allow you to comply with your obligations under the GPSR (e.g., quality controls, complaint handling, knowledge of EU legislation via training of staff on product safety and the introduction of product safety learning paths).

You should **fully cooperate with market surveillance authorities** on product safety aspects (as explained in point 3.4.5.).

It is also important to underline that you can also be designated by the manufacturer to perform the tasks of the responsible person for the product. In this case, you will be subject to the additional obligations of the responsible person as explained in point 3.2.

Check list for the authorised representative

- ✓ **Make sure that you have a written mandate** from the manufacturer specifying the tasks you are asked to perform.
- ✓ **Make sure that you have the capacity to perform the tasks** under the mandate as well your other tasks.
- ✓ **You will be mandated for at least for**:
  - Providing information and documentation to authorities
  - Informing the manufacturer in case of suspicion that its product is dangerous
  - Notifying national authorities about corrective measures taken against dangerous products, via the Safety Business Gateway, if manufacturer has not done so
  - Cooperating with national authorities upon request on action against dangerous products.
- ✓ **Provide a copy of your mandate** upon request of market surveillance authorities.
- ✓ Set up **internal processes for product safety**.
- ✓ **Cooperate fully with national authorities**.
- ✓ **Check whether you are asked to perform the tasks of the responsible person in the EU**, if so, it entails additional tasks for you (see part 3.2).

For more details, refer to the section 3.1.2. on authorised representative's obligations.

[22] See more indications regarding the mandate in the Blue guide on the implementation of EU product rules 2022 (OJ C 247, 29.6.2022, p. 1–152).

3.1.3. I am an importer: what are my obligations under the GPSR?

Who is an importer?

The GPSR defines an importer as any natural or legal person established within the Union who places a product from a third country on the Union market.

The importer is always established in the EU.

What to do before placing a product on the market?

Your overall obligation is to ensure that the product complies with the general safety requirement and that the manufacturer has complied with the requirements on:

- Internal risk analysis and technical documentation (see point 3.1.1)
- Information to be indicated on the product (see point 3.1.1)

What information do I have to indicate on/with the product in addition to the information provided by the manufacturer?

- Your name, registered trade name or registered trademark,
- Your postal and electronic address and, where different, the postal or electronic address of the single contact point at which you can be contacted.

How should the information listed above be displayed?

You have to ensure that consumers can easily see and read this information. This information must be placed on the product or, where that is not possible, on its packaging or in a document accompanying the product. The decision where to display this information is up to your assessment within the framework provided. You should therefore also be able to justify your choice in the case of a dispute. Only the size of the product (and therefore not, for example, aesthetic or similar reasons) could justify moving some required information from the product to its packaging or other accompanying documents. [23]

You must ensure that any additional label to be affixed to the product or packaging by you does not obscure any information required by EU law provided by the manufacturer.

What does "electronic address" mean?

An electronic address can be an e-mail address or dedicated section of your website that enables consumers to contact you directly. A website is not in itself sufficient if it does not allow direct communication with you.

Which instructions and safety information must be provided with the product?

You must ensure that the product you import is accompanied by clear instructions and safety information.

In which language(s) do I have to provide this information?

You must make sure that these instructions and safety information are in a language easily understood by consumers. This is determined by the Member State on the market of which you place the product.

Is this information mandatory in all cases?

No, if the product can be used safely and as you intended without such instructions and safety information, then they are not mandatory. This is the case for instance for products that pose risks that are well known to consumers (e.g., knives).

What are my obligations if I offer a product via distance sales?

If you decide to make products available on the market online or through other means of distance sales, the offer of those products (e.g., a product offer on your e-shop) must clearly and visibly indicate at least the following information:

a. The name, registered trade name or registered trademark of the manufacturer, as well as the postal and electronic address at which they can be contacted;

b. If the manufacturer is not established in the EU, the name, postal and electronic address of the responsible person within the meaning of Article 16(1) of this Regulation or Article 4(1) of Regulation (EU) 2019/1020;

[23] A similar approach is followed also in the guidelines of the Blue Guide on the implementation of the product rules 2022 (OJ C 247, 29.6.2022, p. 1–152).

c. Information allowing the identification of the product, including a picture of it, its type and any other product identifier; and

d. Any warning or safety information to be affixed to the product or to the packaging or included in an accompanying document in accordance with this Regulation or the applicable EU harmonisation legislation in a language which consumers can easily understand, as determined by the Member State in which the product is made available on the market.

What are my obligations if I have a customer loyalty programme in place?

The GPSR sets out new obligations if you have (or plan to have) a **customer loyalty programme** that makes it possible to identify products bought by consumers (e.g., customers have a loyalty card that is scanned when they purchase products, and the history of their purchases is available to the business that has set up the loyalty programme). This excludes customer loyalty programmes that do not enable the identification of products bought by consumers (for example, loyalty cards through which customers can receive some benefits for a certain amount purchased, but for which no data on which products have been bought by the customer are registered)

This is an efficient way to identify customers affected by a product safety recall or a safety warning. However, customers might choose not to use such systems because they are not interested in the other benefits offered by the customer loyalty programme, and might in particular not want to be contacted for marketing purposes.

Under the GPSR, if you have a customer loyalty programme in place, you must give the possibility for consumers to choose to take part in the customer loyalty programme for safety-related purposes only.

This means that customers should have the option of providing their contact details only in order to receive safety information (e.g., product safety recalls or safety warnings). In this case, their data should only be used to contact them in the event of a recall or safety warning and should not be processed for any other purpose (such as marketing).

What are my obligations regarding the storage and transport of products?

While a product is under your responsibility, you have to ensure that storage or transport conditions:

- do not make it dangerous (e.g., if the product must be kept at a certain temperature to remain safe); and
- do not affect the markings required on the product (see point 3.1.1).

What are my obligations regarding the technical documentation?

You must keep a copy of the technical documentation drawn up by the manufacturer (referred to in point 3.1.1), including all related documents, where relevant, for 10 years after you have placed the product on the market.

You must be able to provide this documentation to the national market surveillance authorities upon request.

Additional obligations of the importer

It is also important to underline the point that you can also be the **responsible person of the product**, if the manufacturer is not established in the EU. In this case, you will be subject to additional obligations as explained in point 3.2.

Internal processes: you should have internal processes for product safety in place, that allow you to comply with your obligations under the GPSR (e.g., quality controls, complaint handling, knowledge of EU legislation via training of staff on product safety and the introduction of product safety learning paths).

You should **fully cooperate with market surveillance authorities** on product safety aspects as explained in point 3.4.5.

What should I do if an issue arises with a product before it is placed on the market?

You should not place a product on the market before it has been brought to conformity if you consider or have reason to believe that one or more of the following might be true:

- a product is dangerous (for instance because of an accident reported by a consumer or an actor in the supply chain);
- a product does not comply with the obligations on internal risk analysis and technical documentation (see point 3.1.1);

- a product does not comply with the obligations regarding the information to be indicated on the product (see point 3.1.1).

Bringing the product into conformity might mean, for instance, adding the information that was missing on the product.

If the product is dangerous, you must immediately:

- inform the manufacturer thereof;
- ensure that the market surveillance authorities are informed of this dangerous product through the Safety Business Gateway (see point 3.4.3).

What should I do if a safety issue arises with a product after it has been placed on the market?

If you consider or have reason to believe that a product you placed on the market is dangerous (for instance, because of an accident reported by a consumer or an actor in the supply chain), you must immediately take the following steps:

A) Inform the manufacturer of the safety issue.

This transmission of information is key to addressing the safety issue quickly;

B) Ensure that the manufacturer has taken corrective measures necessary in order to effectively bring the product into conformity.

If such measures are not already been taken by the manufacturer, you must immediately take them.

Examples of corrective measures you can take:

- Recall of the product from end-users (see provisions related to information on recalls, recall notices and remedies in the case of a recall in point 3.4.1);
- Withdrawal of the product from the market;
- Destruction of the product;
- Stop of sales;
- Marking the product with appropriate warnings on the risks; or
- Warning consumers of the risks.

You should monitor the effectiveness of the measures you take and adapt them if necessary. You may have to take several measures simultaneously.

C) Ensure that consumers are informed about the dangerous product(s).

If the manufacturer has not yet informed consumers, you must do so yourself.

How should I inform consumers?

You can use the Safety Business Gateway to alert authorities and consumers at the same time (but the information provided can be different in terms of details and technicality). Information submitted via the Safety Business Gateway and intended for the public will be made available to consumers on the Safety Gate Portal.

Informing consumers about product safety recalls and safety warnings :

If the manufacturer has not already done so, you must yourself inform consumers about product safety recalls or safety warnings, to ensure the safe use of a product (see specific provisions in point 3.4.1)

D) Inform the market surveillance authorities of the Member States in which the product has been made available on the market.

How should I inform market surveillance authorities?

You must use the Safety Business Gateway to alert market surveillance authorities. This tool enables you to select all the Member States in which the dangerous product has been made available and to inform authorities immediately.

What type of information do I have to communicate to consumers and to authorities?

You must give details of:

1. the risk to the health and safety of consumers: describe in a clear and understandable way what can happen with the product;
2. any corrective measure already taken; and
3. if available, the quantity, by Member State, of products still circulating on the market.

What are my obligations regarding complaints and accidents?

A. Ensure the existence of a channel for consumer complaints

You must verify that the manufacturer has provided consumers with a communication channel (e.g., a telephone number, electronic address or a dedicated section of a website) that enables consumers to submit complaints and to inform the manufacturer of any accident or safety issue they have experienced with a product.

In the absence of such channels, you must provide one for consumers.

These channels should take into account the accessibility needs of persons with disabilities. For instance, you should not provide all relevant information in an image that cannot be read by a text-to-audio machine. [24]

B. Investigate complaints and keep other actors in the supply chain informed

If you receive a complaint from a consumer or information about an accident concerning the safety of a product, you must investigate it. If it appears justified, you should adopt a corrective measure.

You must inform the manufacturer, distributors and, where relevant, fulfilment service providers and providers of online marketplaces in a timely manner, of the investigation you performed and of the results of the investigation.

For each product, you must keep an internal register of:

a. consumer complaints;

b. product recalls; and

c. any corrective measures taken to bring the product into conformity.

In this internal register of complaints, you should only store the personal data you need in order to investigate a complaint.

Such data should only be kept as long as is necessary for the purposes of the investigation. In any case, you should delete personal data (e.g., the consumer's name and address) from the register 5 years after the data have been entered into it.

C. Keep the manufacturer informed of any accident caused by a product and ensure that competent authorities are notified

If you have **knowledge of an accident caused by a product** that you made available on the market, you should inform the manufacturer of this without undue delay. The manufacturer may instruct you to notify the competent authorities.

If you have **knowledge of an accident and the manufacturer of the product** is not established in the EU, you should inform the responsible person of the product in the EU. This responsible person must ensure that the accident is notified to the competent authorities of the Member State where the accident has occurred.

What constitutes an accident related to the safety of products?

Accidents that must be notified refer to occurrences associated with the use of a product that resulted in an individual's death or in serious adverse effects on that individual's health and safety. These effects can be permanent or temporary, and can include injuries, other damage to the body, illnesses and chronic health effects.

Which tool do I have to use to notify the accident?

You must use the Safety Business Gateway (see point 3.4.3).

What type of information do I have to include in the notification?

You must specify:

- the type and identification number of the product; and
- the circumstances of the accident, if known.

Check list for the importer

Before placing the product on the market:

✓ **Ensure the product is safe**.

✓ **Ensure the manufacturer did the risk assessment and drew up the technical documentation. Keep this technical documentation for 10 years** and provide it to authorities upon request.

✓ **Ensure that** the product identification details, the manufacturer's identification and contact details, are **correctly affixed to the product or its packaging**, and that the product is accompanied by instructions and safety information if needed.

[24] The accessibility requirements of Annex I of Directive 2019/882 (Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the accessibility requirements for products and services (OJ L 151, 7.6.2019, p. 70–115)), are compulsory and are to be implemented in order to reflect your products' foreseeable use of persons with disabilities.

- ✓ **Add your identification and contact details on/ with the product**. Ensure that this information **does not obscure any other mandatory information**.
- ✓ **Ensure that there is a responsible person for the product in the EU** and that its contact details and other required information are indicated on the product or on its packaging, the parcel or an accompanying document. It can be you!
- ✓ Set up **internal processes for product safety**.
- ✓ **Ensure that storage or transport do not affect product safety or its labelling**.
- ✓ **Don't place a non-conform or dangerous product on the market!** In case of any non-conformity **inform the manufacturer and the market surveillance authorities**.

After placing of the product on the market:

- ✓ **If product safety issue arises**:
  - **Inform the manufacturer**
  - **Ensure that the manufacturer has taken corrective measures** (for recalls it used the template recall notice and provided remedies). **If not, you must immediately take them**.
  - **Ensure that the manufacturer informed consumers about dangerous products. If not, you must do so**.
  - **Inform national authorities via the Safety Business Gateway**.
- ✓ Ensure that the manufacturer has a **direct channel for consumer complaints** about product safety. If not, you must provide it. Think about accessible formats.
- ✓ **Investigate any complaints and keep other actors in the supply chain informed**.
- ✓ **Keep internal register** of consumer complaints, product recalls and corrective measures taken.
- ✓ **Report product-related accidents** you become aware of, **to the manufacturer and to the responsible person for the product in the EU**. The manufacturer can instruct you to notify it to authorities via the **Safety Business Gateway**.
- ✓ **Cooperate with market surveillance authorities** when requested.

For more details, refer to the section 3.1.3. on importer's obligations.

3.1.4. I am a distributor: what are my obligations under the GPSR?

Who is a distributor?

The GPSR defines a distributor as *any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market*.

Making available on the market means *any supply of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.*

For example, a distributor can be a business that makes a manufacturer's product available on the market with packaging translated for a specific EU country, as long as it is still sold under the manufacturer's name or trademark.

Before making the product available on the market:

1. You should **verify whether the manufacturer and importer (where applicable) have complied with the following requirements regarding the product you intend to distribute**:

   a) That the product bears a type, batch or serial number or other element enabling the identification of the product which is easily visible and legible for consumers, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product.

   b) That the manufacturer has indicated its name, its registered trade name or registered trademark, its postal and electronic address and, where different, the postal or electronic address of the single contact point where it can be contacted. That information should be placed on the product or, if that is not possible, on its packaging or in a document accompanying the product.

   c) That the product is accompanied by clear instructions and safety information in a language which consumers can easily understand, as determined by the Member State in which the product is made available on the market. This is not required if the product can be used safely and as intended by the manufacturer without such instructions and safety information.

d) If an importer is involved in the supply chain, that the importer has indicated its name, its registered trade name or registered trademark, its postal and electronic address and, where different, the postal or electronic address of the single contact point where it can be contacted. That information must be placed on the product or, where that is not possible, on its packaging or in a document accompanying the product.

e) That there is no additional label obscuring any information required by EU law on the label provided by the manufacturer or the importer.

2. You should make sure that, while a product is under your responsibility, **storage or transport conditions do not jeopardise its conformity with the general safety requirement laid down in Article 5 of the GPSR**.

*If you consider or have reason to believe, on the basis of the information in your possession, that **a product is dangerous or not in conformity with the requirements in point 1 just above, you should not make the product available on the market** unless the product has been brought into conformity.*

3. **Internal processes**: you should have internal processes for product safety in place, that allow you to comply with your obligations under the GPSR (e.g., quality controls, complaint handling, knowledge of EU legislation via training of staff on product safety and the introduction of product safety learning paths).

What should you do in case you offer a product via distance sales?

If you decide to make products available on the market online or through other means of distance sales, the offer of those products (e.g., a product offer in your e-shop) must clearly and visibly indicate at least the following information:

a. Name, registered trade name or registered trademark of the manufacturer, as well as the postal and electronic address at which they can be contacted;

b. If the manufacturer is not established in the EU, the name, postal and electronic address of the responsible person within the meaning of Article 16(1) of this Regulation or Article 4(1) of Regulation (EU) 2019/1020;

c. Information allowing the identification of the product, including a picture of it, its type and any other product identifier; and

d. Any warning or safety information to be affixed to the product or to the packaging or included in an accompanying document in accordance with this Regulation or the applicable EU harmonisation legislation in a language which consumers can easily understand, as determined by the Member State in which the product is made available on the market.

After making the product available on the market:

You should **fully cooperate with market surveillance authorities** on product safety aspects as explained in point 3.4.5.

If you consider or have reason to believe on the basis of the information in your possession, that **a product you have made available on the market is dangerous or not in conformity with the requirements in point 1 above**, you must immediately take the following steps:

A) **Inform the manufacturer or the importer, as applicable, of this**.

This transmission of information is key to addressing the safety or non-compliance issue quickly.

B) **Ensure that the corrective measures necessary to effectively bring the product into conformity are taken**, including withdrawal or recall, if appropriate. If you initiate a recall, refer to point 3.4.1; and

C) **Ensure that the market surveillance authorities of the Member States in which the product has been made available on the market are immediately informed** of this through the Safety Business Gateway.

How should I inform market surveillance authorities?

You have to use the Safety Business Gateway. This tool enables you to select all the Member States in which the dangerous product has been made available and to inform authorities immediately and simultaneously.

What type of information do I have to communicate to authorities?

For the purposes of points B) and C) you should give appropriate details available to you of:

1) the risk to the health and safety of consumers by describing in a clear and understandable way what can happen with the product;

2) any corrective measure already taken; and

3) if available, the quantity, by Member State, of products still circulating on the market.

D) **Keep the manufacturer informed of any accident caused by a product and ensure that the competent authorities are notified**

If you have **knowledge of an accident caused by a product** that you made available on the market, you should inform the manufacturer without undue delay. The manufacturer may instruct you to notify the competent authorities.

If you have knowledge of an accident and the manufacturer of the product is not established in the EU, you should inform the responsible person of the product in the EU. This responsible person must ensure that this accident is notified to the competent authorities of the Member State where the accident has occurred.

What constitutes an accident related to the safety of products?

Accidents that must be notified concern occurrences associated with the use of a product that resulted in an individual's death or in serious adverse effects on an individual's health and safety. These effects can be permanent or temporary. They can include injuries, other damage to the body, illnesses and chronic health effects.

Which tool do I have to use to notify the accident?

You must use the Safety Business Gateway (see point 3.4.3).

What type of information do I have to include in the notification?

You must specify:

- the type and identification number of the product; and
- the circumstances of the accident, if known.

Check list for the distributor

Before making the product available on the market:

- **Verify** that the product identification details, the manufacturer's and importer's identification and contact details are correctly affixed to the product or its packaging and that the product is accompanied by instructions and safety information if needed.
- Verify that no **labels obscure any other mandatory information**.
- **Ensure that storage or transport does not affect product safety or its labelling.**
- Set up **internal processes for product safety.**
- **Display the required product information in distance sales offers**:
  - product identification details and its picture,
  - identification and contact details of the manufacturer,
  - identification and contact details of the responsible person for the product in the EU,
  - instructions and safety information if needed.
- If you have a **registration scheme or a customer loyalty programme** in place, you must offer the possibility for consumers to subscribe for safety-related purposes only.
- **Don't make a non-conform or dangerous product available on the market!** In case of any non-compliance **inform the manufacturer and authorities**.

After making the product available on the market:

- **If a product you made available is dangerous or non-compliant:**
  - **Inform the manufacturer or the importer**
  - **Ensure the manufacturer or importer have taken necessary corrective measures** (for recalls ensure that they used the template recall notice and provided remedies).
  - **Ensure that national authorities are immediately informed via the Safety Business Gateway**. If they have not been informed by the manufacturer or importer, do it.
  - **Manufacturer and importer must inform consumers about dangerous products**. Be cooperative and proactive in the information dissemination.

- **Report product-related accidents** you become aware of **to the manufacturer and to the responsible person for the product in the EU**. The manufacturer can instruct you to notify it to authorities via the **Safety Business Gateway**.
- **Cooperate with market surveillance authorities** when requested.

For more details, refer to the section 3.1.4. on distributor's obligations.

3.1.5. I am a fulfilment service provider: what are my obligations under the GPSR?

Who is a fulfilment service provider?

The GPSR defines a fulfilment service providers as *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 as defined in Article 2, point (1) of Directive 97/67/EC of the European Parliament and of the Council parcel delivery services as defined in Article 2, point (2) of Regulation (EU) 2018/644 of the European Parliament and of the Council, and any other postal services or freight transport services*.

This means the following: if a business that normally provides only intermediation services (provider of online marketplace), but also provides warehousing and packaging services for some products, it will be considered an economic operator for these products (fulfilment service provider).

It is important to underline the point that **fulfilment service providers are considered as economic operators** under the GPSR. You therefore have to comply with the following generally applicable obligations of economic operators:

- **Internal processes**: you should have internal processes for product safety in place, allowing you to fulfil your obligations under the GPSR (e.g., quality controls, complaint handling, knowledge of EU legislation via training of staff on product safety and the introduction of product safety learning paths); and
- You should **fully cooperate with market surveillance authorities** on product safety aspects (as explained in point 3.4.5).

It is also important to underline the point that, as a **fulfilment service provider you can automatically become the responsible economic operator for the product** (see point 3.2 for more details) if there is no EU manufacturer, importer or authorised representative of a product mandated for this task. In such case, you are subject to additional obligations (as explained in point 3.2).

Check list for the fulfilment service provider

- Set up internal processes for product safety.
- If you notice any safety issue or product non-compliance inform the manufacturer and authorities.
- Don't forget that you can be automatically a responsible person in the EU for certain products you handle! Verify it and if yes, make sure that you have capacity to perform these tasks.
- Cooperate with market surveillance authorities when requested.

For more details, refer to the section 3.1.5. on fulfilment service provider's obligations.

3.2. Economic operator also assuming the role of the responsible person

A product covered by the GPSR cannot be placed on the market without an economic operator established in the EU, the 'responsible person' , who is responsible for performing the tasks set out in Article 4(3) of Regulation (EU) 2019/1020 and in Article 16 of the GPSR in respect to that product.

Who is the responsible person?

The responsible person is any of the following:

(a) a manufacturer established in the EU;

(b) an importer, if the manufacturer is not established in the EU;

(c) an authorised representative who has a written mandate from the manufacturer that designates it to perform the tasks of the responsible person on the manufacturer's behalf;

(d) a fulfilment service provider established in the EU with respect to the products it handles, if no other economic operator as mentioned in points (a), (b) and (c) is established in the EU.

What are your tasks as responsible person?

As a responsible person, you have **additional obligations** on top of those you already have as an economic operator under the different categories explained above. You have the following additional tasks:

(a) Verifying that the technical documentation has been drawn up and ensuring that the technical documentation can be made available to the market surveillance authorities upon request.

(b) Further to a reasoned request from a market surveillance authority, providing that authority with all information and documentation necessary to demonstrate the conformity of the product in a language which that authority can easily understand.

(c) Informing the market surveillance authorities if you have reason to believe that a product presents a risk.

(d) Cooperating with the market surveillance authorities (including following a reasoned request):

i. to make sure that immediate, necessary and corrective action is taken to remedy any case of non-compliance with the requirements set out in the GPSR; or

ii. if that is not possible, to mitigate the risks presented by that product, when required to do so by the market surveillance authorities or on your own initiative, if you consider or have reason to believe that the product in question presents a risk.

(e) Where appropriate with regard to the possible risks related to a product, regularly checking:

i. that the product complies with the technical documentation drawn up by the manufacturer. This means that the possible risk(s) the product might pose have been eliminated or mitigated by the manufacturer as described in the technical documentation, e.g., by applying relevant European standards or other means; and

ii. that the product complies with the following requirements:

- That the product bears a type, batch or serial number or other element that makes it possible to identify the product, and which consumers can easily see and read. Alternatively, if the size or nature of the product does not allow this, the required information must be provided on the packaging or in a document accompanying the product.
- That the manufacturer has indicated its name, its registered trade name or registered trademark, its postal and electronic address and, where different, the postal or electronic address of the single contact point where it can be contacted. That information should be placed on the product or, if that is not possible, on its packaging or in a document accompanying the product.
- That the product is accompanied by clear instructions and safety information in a language which consumers can easily see and read as determined by the Member State in which the product is made available on the market. That requirement does not ap-

ply if the product can be used safely and as intended by the manufacturer without such instructions and safety information.

You should, upon request by the market surveillance authorities, provide documented evidence of the checks performed.

(f) Ensuring your name, registered trade name or registered trademark, and contact details (including the postal and electronic address) are indicated on the product or on its packaging, the parcel or an accompanying document; and

What does "electronic address" mean?

An electronic address can be an e-mail address or dedicated section of your website that enables consumers to contact you directly. A website as such is not sufficient if it does not allow direct communication with you.

(g) If you have knowledge of an accident caused by a product that you are responsible for, ensuring that this accident is notified through the Safety Business Gateway without undue delay from the moment you know about the accident, to the competent authorities of the Member State where the accident has occurred. The notification must include the type and identification number of the product as well as the circumstances of the accident, if known. You should notify any other relevant information to the competent authorities upon request.

For further specifications on the roles of responsible persons, please see the Commission " *Guidelines for economic operators and market surveillance authorities on the practical implementation of Article 4 of Regulation (EU) 2019/1020 on market surveillance and compliance of products*" ([25]).

Check list for the responsible person in the EU

- **Verify that the technical documentation has been drawn up** by the manufacturer and make sure you can provide it to authorities upon request.
- **Ensure your identification and contact details are indicated on/with the product**.
- **Regularly check that the product complies with the technical documentation**: this means that the possible risk(s) the product might pose have been well eliminated or mitigated by the manufacturer as described in the technical documentation.
- **Regularly check that the product identification details, the manufacturer's and importer's identification and contact details are correctly affixed to the product or its packaging and accompanied by instructions and safety information if needed**.
- **Cooperate with market surveillance authorities** and provide them all information and documentation, when requested.
- **If you become aware that a product presents a safety risk**:
  - **inform national authorities via the Safety Business Gateway;**
  - **inform the manufacturer;**
  - **make sure that corrective action is immediately taken. If the manufacturer hasn't done so, do it yourself!**
- **Report product-related accidents** you become aware of via the **Safety Business Gateway**.
- **Fulfil the obligations that you have as a manufacturer, importer, authorised representative or fulfilment service provider**.

For more details, refer to the section 3.2. on the obligations of the responsible person in the EU.

[25] Commission Notice Guidelines for economic operators and market surveillance authorities on the practical implementation of Article 4 of Regulation (EU) 2019/1020 on market surveillance and compliance of products (OJ C 100, 23.3.2021, p. 1–15).

3.3. Providers of online marketplaces

What is a provider of an online marketplace?

A 'provider of an online marketplace' means a provider of an intermediary service who uses an online interface which allows consumers to conclude distance contracts with traders for the sale of products. These businesses therefore only provide online intermediation services for a given product.

If your business also provides one or more of the services of economic operators, it then acts in that capacity instead and is subject to the obligations of the relevant economic operator. If a business also provides economic operator services for a given product, please consult point 3.1 and 3.2 of this guidance.

What are my obligations under the GPSR as a provider of an online marketplace?

It is important to underline the point that the obligations of providers of online marketplaces linked to product safety under the GPSR complement and further specify some of their obligations under the Digital Services Act ('DSA') [(26)].

The following obligations, which are outlined in Chapter IV of the GPSR, concern all providers of online marketplaces except that those marked with an asterisk (*) are only relevant for (i) medium or large enterprises and (ii) micro/small enterprises where these micro and small enterprises have been designated as a 'very large online platform or search engine' withing the meaning of the DSA [(27)].

[(26)] Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act) (OJ L 277, 27.10.2022, p. 1–102).

[(27)] Article 22 para 7, 9 and 11 of GPSR include specifications of certain DSA obligations, namely Articles 23 and 31 thereof, and therefore follow the scope of application of the latter. Pursuant to Article 19 (re Article 23 and more generally the obligations in section 3 of Chapter III DSA) and 29 DSA (re Article 31 and more generally the obligations in section 4 of Chapter III DSA), these obligations are in principle not applicable to providers of platforms that qualify as Micro and Small Enterprises (SMicE). However, both Articles 19(2) and 29(2) of the DSA include a derogation to this principle, such that a SMicE platform which is at the same time designated as VLOP/VLOSE is indeed subject to these obligations. The statement in the table therefore means that the specifications of the DSA obligations included in the GPSR applies to any platform provided by medium and large enterprises (as normally provided under Articles 19 and 29 of the DSA), as well as to any platform provided by a SMicE that is at the same time designated as VLOP/VLOSE, because in that case the exclusion from application of sections 3 and 4 of DSA does not apply.

Your obligations as a provider of an online marketplace under the GPSR are the following:

- You should designate a **single point of contact** that allows for direct communication, by electronic means, **with Member States' market surveillance authorities** in relation to product safety issues.
- You should **register with the Safety Gate Portal** and should indicate on the Safety Gate Portal the information concerning your single contact point.
- You should **designate a single point of contact to enable consumers to communicate directly** and rapidly with you in relation to product safety issues.
- You should ensure that you have **internal processes** for product safety in place in order to comply without undue delay with the relevant requirements of the GPSR. These internal processes should include mechanisms which enable traders (your business partners) to provide:
  - the required product safety and traceability information; and
  - their self-certification in which they make a commitment to offer only products that comply with EU product safety rules and additional identification information in line with the DSA requirements.
- You should take the necessary measures to **receive and process orders** issued by national authorities and you should act without undue delay (and in any event within **2 working days** of receipt of the order). You should inform the issuing market surveillance authority of the effect given to the order by electronic means using the contact details of the market surveillance authority published on the Safety Gate Portal. Such an order might require you to, for a prescribed period, **to remove from your online interface all identical content** referring to an offer of the dangerous product in question, to disable access to it or to display an explicit warning.
- You should **take into account regular information on dangerous products that have been notified by the market surveillance authorities**, received through the Safety Gate Portal. This will help you to apply **your voluntary measures** to detect, identify, remove or disable access to the content referring to offers of dangerous products

on your online marketplace, where applicable, (including by making use of the interoperable interface to the Safety Gate Portal). You should inform the market surveillance authority that made the notification to the Safety Gate Rapid Alert System of any measures you have taken, by using the market surveillance authority's contact details published in the Safety Gate Portal.

- You should be able to **receive notices related to product safety issues** from any third parties (including consumers and consumer organisations), and **process these without undue delay and in any event within 3 working days** from the receipt of the notice.
- (*) Regarding product safety, you should **use at least the information in the Safety Gate Portal for the purpose of compliance with the required ex-post random checks** under Article 31(3) of the DSA.
- (*) Regarding product safety, you should **suspend, for a reasonable period of time** and after having issued a prior warning, the provision of your services to **traders that frequently offer unsafe products**.
- (*) As regards product safety information, you should **design and organise your online interface** in a way that **enables traders offering the product to provide at least the following information for each product offered and that ensures that the information is displayed** or otherwise made easily accessible by consumers on the product listing:
  - the name, registered trade name or registered trademark of the manufacturer, as well as the postal and electronic address at which the manufacturer can be contacted;
  - if the manufacturer is not established in the EU, the name, postal and electronic address of the responsible person within the meaning of Article 16(1) of the GPSR or Article 4(1) of Regulation (EU) 2019/1020;
  - information allowing the identification of the product, including a picture of it, its type and any other product identifier; and
  - any warning or safety information to be affixed the product or to accompany it in accordance with the GPSR or the applicable EU harmonisation legislation in a language which can be easily consumers can easily understand as determined by the Member State in which the product is made available on the market.
- You should **cooperate with the market surveillance authorities, with traders and with relevant economic operators** regarding the safety of products offered online through your services. This should consist of the following in particular:
  - Cooperating on **product recalls** by:
    - directly notifying all affected consumers who bought the relevant product through your interfaces;
    - publishing information on product safety recalls on your online interfaces; and
    - generally, cooperating in the interest of effective product recalls.
  - Informing the relevant economic operators if you removed an offer of a product that concerns them.
  - Providing information to national authorities on dangerous products via the Safety Business Gateway.
  - Cooperating with economic operators and market surveillance authorities on **accidents** notified to you.
  - Cooperating with other relevant authorities including law enforcement agencies on unsafe products and **in identifying the relevant supply chain**.
  - Allowing data scrapping for product safety purposes if so requested by a market surveillance authority, and generally allowing the online tools operated by market surveillance authorities to identify dangerous products to **access to your interfaces**.

In order to facilitate the compliance with your obligations the Commission has developed an interoperable interface of the Safety Gate Portal, which allows providers of online marketplaces to link in their interfaces.

Best practices

- Providers of online marketplaces are encouraged to join relevant Memorandums of Understanding that concern product safety, (e.g., the Product Safety Pledge+) [(28)].
- Providers of online marketplaces are encouraged to check products with the Safety Gate Portal before placing them on their interface.

[(28)] https://ec.europa.eu/safety-gate/#/screen/pages/productSafetyPledge.

Check list for the providers of online marketplaces

- **Designate a single point of contact** allowing for direct communication, by electronic means, with national authorities and with consumers (it can the same single contact point or two different ones).
- **Register with the Safety Gate Portal.**
- **Set up internal processes for product safety**. These should include mechanisms allowing traders to provide required product safety and traceability information, their self-certification and other DSA requirements.
- **Ensure you can receive and process orders issued by national authorities** and take required action without undue delay, and in any event **within 2 working days. Report back to authorities. Track and disable access to listings with identical product, when so required by the orders**.
- **Take into account information on dangerous products from the Safety Gate Portal in your existing tracking or due diligence mechanisms.**
- **Ensure you can receive notices about product safety issues from third parties and process these without undue delay** and in any event **within 3 working days**.
- **Cooperate with market surveillance authorities, with traders and with relevant economic operators.**

Additional obligations for medium or large enterprises and micro/small enterprises where these micro and small enterprises have been designated as a 'very large online platform or search engine' withing the meaning of the DSA:

- **Use the Safety Gate Portal information for the required ex post random checks.**
- **Suspend, for a reasonable period of time** and after having issued a prior warning, the provision of services to **traders that frequently offer unsafe products**.
- **Design and organise your online interface** to **enable traders to provide at least the following information for each product offered and that ensures that the information is displayed** or made easily accessible by consumers on the product listing:
  - product identification details and its picture;
  - identification and contact details of the manufacturer;
  - identification and contact details of the responsible person for the product in the EU; and
  - instructions and safety information if needed.

For more details, refer to the section 3.3. on the obligations of providers of online marketplaces.

3.4. General obligations and tools

3.4.1. Informing consumers about product safety recalls and safety warnings

Depending on your respective obligations under the GPSR (see points 3.1 to 3.3 above), you can be required to ensure the safe use of a product by informing consumers about product safety recalls or safety warnings.

Direct communication with consumers is the most effective way for consumers to be informed and react to recalls and safety warnings.

When is direct communication to consumers an obligation?

Direct communication to consumers is mandatory if consumers are affected by a product safety recall or if certain information has to be brought to the attention of consumers for the safe use of a product (safety warning).

This identification of affected consumers can be done in one of two ways:

- directly by you, through customers' personal data that you have collected; or
- through a third party (e.g., a specific entity in charge of collecting data on users of motor vehicles).

Do I have to inform the consumers directly?

Your obligation is to ensure that consumers are notified directly and without undue delay about the product safety recall or the safety warning, but the actor that will inform consumers may vary:

- As a general rule, the actor in the supply chain that has access to customers' personal data (e.g., through purchase data, customer loyalty programmes or registration schemes) should be the one contacting them. Cooperation in the supply chain is therefore essential when product safety recalls or safety warnings are at stake.
- Alternatively, consumers may be informed by a third party that has access to their contact details (e.g., the entity in charge of collecting data on users of motor vehicles).

Is this obligation compatible with personal data requirements?

Yes, the legal obligation requiring economic operators and providers of online marketplaces to use any customer data already at their disposal to inform consumers of recalls and safety warnings is fully compatible with the EU's personal data legislation.

You should reflect this obligation in your privacy statement and other personal data information provided to customers.

Do I have to inform consumers only, or do I also have to inform companies that have purchased the product that is the subject of the product safety recall or the safety warning?

Even when product safety recalls and safety warnings are primarily targeted at consumers, this should not prevent you from informing all types of customers, especially in the case of micro- and small enterprises acting like consumers.

What are the rules regarding registration schemes and customer loyalty programmes?

The GPSR sets out new obligations if you have (or plan to have):

- a **registration scheme**, through which consumers, after purchasing a product, voluntarily communicate some information (e.g., their name, contact information, the product model or serial number), to the manufacturer and might as a result get some benefits; or
- a **customer loyalty programme** that makes it possible to identify products bought by consumers (e.g., customers have a loyalty card that is scanned when they purchase products, and the history of their purchases is available to the business that has set up the loyalty programme). This excludes customer loyalty programmes that do not enable the identification of products bought by consumers, (e.g., loyalty cards whereby customers receive some benefits for a certain amount purchased, but no data is registered as regards which products have been bought by the customer).

Both systems are efficient ways to identify customers affected by a product safety recall or a safety warning. However, customers might choose not to use them because they are not interested in the other benefits offered by the registration scheme or the customer loyalty programme, and in particular because they might not want to be contacted for marketing purposes.

Under the GPSR, if you have a registration scheme or a customer loyalty programme in place, you must allow consumers to choose to register with the registration scheme or to take part in the customer loyalty programme for safety-related purposes only.

This means that customers must have the possibility to provide their contact details with the sole purpose of receiving safety information (e.g., product safety recalls or safety warnings). In this case, their data should only be used to contact them in the event of a recall or safety warning and should not be processed for any other purpose (such as marketing).

Do I have other obligations to inform consumers?

It is sufficient for you to be sure that all the affected consumers have been directly contacted to get information about the product safety recall or safety warning. However, this may only be possible for products with small production batches or for which consumer data are easily available.

In all other cases, you have to disseminate a clear and visible recall notice (see point 3.4.1) or safety warning through other appropriate channels, ensuring the widest possible reach. This includes, where available, your company's website, social media channels, newsletters and retail outlets and, as appropriate, announcements in mass media and other communication channels.

Recall notice

Information on a product safety recall provided to consumers in a written form must take the form of a recall notice. This recall notice must be easily understood by consumers and available in the language(s) of the Member State(s) where the product has been made available on the market.

The GPSR lists the elements the recall notice must contain:

- a headline consisting of the words 'Product safety recall';
- a clear description of the recalled product, including:
  - the picture, name and brand of the product;
  - product identification numbers (e.g., batch or serial number), and, if applicable, a graphical indication of where to find them on the product; and
  - information (if available) on when, where and by whom the product was sold;
- a clear description of the hazard associated with the recalled product, avoiding any elements that may decrease consumers' perception of risk, (e.g., by using terms and expressions such as 'voluntary', 'precautionary', 'discretionary', 'in rare situations' or 'in specific situations' or indicating that there have been no reported accidents);
- a clear description of the action consumers should take, including an instruction to immediately stop using the recalled product;
- a clear description of the remedies available to consumers;
- a free phone number or interactive online service, where consumers can get more information in a relevant official language(s) of the EU;
- encouragement to share the information about the recall with other persons, if appropriate.

A template [(29)] for recall notices has been set out in Commission Implementing Regulation (EU) 2024/1435 and is available on the Safety Gate Portal in a format that enables economic operators to easily create a recall notice.

[(29)] In the Annex of Commission Implementing Regulation (EU) 2024/1435 of 24 May 2024 laying down rules for the application of Regulation (EU) 2023/988 of the European Parliament and of the Council as regards establishing the template for a recall notice (OJ L, 2024/1435, 27.5.2024, p.1).

How do I make information accessible to persons with disabilities?

Under the GPSR, you have the obligation to make recall information accessible to persons with disabilities. [30] For instance when a recall notice is shared online, it should take into account best practices for web accessibility. If important information about the recalled product or the identification of the products concerned by the recall is contained in a picture, this should also be spelled out in order to be machine-readable. When possible, the image should allow for flexible adjustments in magnification, brightness, and contrast. Additionally, it should ensure interoperability with programmes and assistive devices for navigating the notice.

3.4.2. What kind of remedies should I offer to consumers if I initiate a product safety recall?

In the event of a product recall, you must offer the consumer a choice between at least two of the following remedies:

- the **repair** of the recalled product;
- a **replacement** of the recalled product with a safe one of the same type and at least the same value and quality; or
- an adequate **refund** of the value of the recalled product. In this case, the amount of the refund must be at least equal to the price paid by the consumer. Further compensation might be provided for in national laws.

You may offer additional incentives (e.g., discounts or vouchers) to encourage consumers to participate in the recall.

As an exception, you may offer the consumer only one remedy if:

- other remedies would be impossible; or
- compared with the proposed remedy, the other remedies would impose costs that would be disproportionate.

This should be assessed taking into account all circumstances, including whether the alternative remedy could be provided without significant inconvenience to the consumer.

In any case, the remedy should always be effective, cost-free and timely. It should **not entail significant inconvenience for the consumer**. The consumer should not bear the costs of shipping or otherwise returning the product. For products that are not portable by their nature, you should arrange for the collection of the product.

In which cases does the consumer automatically have the right to a refund?

If you have not completed the repair or replacement within a reasonable time and without significant inconvenience to the consumer, the consumer is entitled to a refund of the product's value.

Can I ask consumers to repair or dispose of a dangerous product themselves?

You can ask consumers to repair the product if they can do this easily and safely, (e.g., changing the battery on a laptop, which would require no special skills). This must be clearly described in the recall notice. You must provide consumers with the necessary instructions and, where relevant, free replacement parts or software updates.

You might include the disposal of the dangerous product by consumers among the actions to be taken if they can easily and safely dispose of it. This should not be the case for instance if the product poses a risk of fire after it has been disposed of.

What is the link with Directives (EU) 2019/770 [31] and (EU) 2019/771 [32] ?

Directives (EU) 2019/770 and (EU) 2019/771 set out contractual remedies in the case of a lack of conformity of the goods with the contract. The provisions on remedies in the GPSR aim to ensure the elimi-

[30] It should be noted that the products that are covered in the scope of the European Accessibility Act (Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the accessibility requirements for products and services (OJ L 151, 7.6.2019, p. 70–115)), need to comply with its accessibility requirements. The directive requires economic operators to ensure that these products are accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users. This includes persons with disabilities and that information is to be accessible by complying with the accessibility requirements of Annex I of the Directive.

[31] Directive (EU) 2019/770 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the supply of digital content and digital services (OJ L 136, 22.5.2019, p. 1–27).

[32] Directive (EU) 2019/771 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the sale of goods, amending Regulation (EU) 2017/2394 and Directive 2009/22/EC, and repealing Directive 1999/44/EC (OJ L 136, 22.5.2019, p. 28–50).

nation of dangerous products from the market and an adequate remedy for the consumer. The specific features of the GPSR compared with Directives (EU) 2019/770 and (EU) 2019/771 are the following:

- in the event of a product recall under the GPSR, there are no time limitations to activate the remedies;
- the consumer is entitled to request remedies from the relevant economic operator responsible for the recall, not necessarily from the trader; and
- in the event of a product safety recall, the consumer does not have to prove that the product is dangerous.

Consumers can choose to use either remedies provided in the event of a recall of a dangerous product under the GPSR or remedies for non-conformity of goods with the contract.

Example: *in the case of a product safety recall initiated by the manufacturer, consumers can claim remedies based on the recall notice or they can ask for remedies from the seller that are based on the dangerous good's non-conformity with the contract, if applicable.*

In any case:

- once consumers have been provided with a remedy under the GPSR, they cannot claim a remedy for non-conformity of the good with the contract because the product was dangerous; and
- once consumers have been provided with a remedy under Directive (EU) 2019/770 or Directive (EU) 2019/771, they cannot claim a remedy under the GPSR for the same safety issue.

However, if a remedy has been provided to the consumer following a recall of a dangerous product, but other requirements for conformity regarding the same good are not fulfilled, the seller remains liable for such non-conformity of the good with the contract.

3.4.3. What is the Safety Business Gateway?

The Safety Gate comprises three elements:

- The rapid alert system on dangerous non-food products whereby national authorities and the Commission can exchange information on such products (**Safety Gate Rapid Alert System**);
- A web portal to inform the public about measures taken against dangerous products and enable them to submit complaints, as well as allowing providers of online marketplaces to register their contact point (**Safety Gate Portal** [33]);
- A web portal to enable businesses to comply with their obligation to inform authorities and consumers of dangerous products and accidents (**Safety Business Gatewa**y).

The **Safety Gate Rapid Alert System** is the platform through which authorities and the Commission exchange information on measures taken against dangerous non-food products. The system contains both public information and restricted confidential data, the latter being accessible only to registered authorities.

An extract of alert information from the Rapid Alert System is published on the **Safety Gate Portal** in order to inform the general public about dangerous products. **Providers of online marketplaces** must register their contact points on the Safety Gate Portal to facilitate communication with authorities regarding product safety issues. Registered providers of online marketplaces may request interoperability credentials, enabling them to automatically receive new alerts, immediately after their publication on the Safety Gate Portal.

The **Safety Business Gateway** is a tool that businesses must use to inform the market surveillance authorities about:

- dangerous products they have made available on the market; and/or
- accidents that have occurred in relation to such products.

The Safety Business Gateway is available on the Safety Gate Portal [34].

What type of information do I have to enter to the Safety Business Gateway?

In order to submit a notification via the Safety Business Gateway, you have to create an EU Login account or log into your existing EU login account.

You then have to encode in the Safety Business Gateway information to identify the product, detail

[33] The Safety Gate Portal can be accessed here: https://ec.europa.eu/safety-gate/

[34] https://webgate.ec.europa.eu/safety-business-gateway/

the product risk or the accident that has occurred, and indicate information about the supply chain of the product.

What happens to the information entered? Does it automatically become a notification in the Safety Gate Rapid Alert System?

The information entered in the Safety Business Gateway is immediately made available to all relevant market surveillance authorities.

If the relevant criteria are met, the authority may decide to create a notification in the Safety Gate Rapid Alert System based on the information provided.

If you submitted a risk assessment, this is only indicative for the responsible authority, which can assess the risk level differently.

Can I use the Safety Business Gateway to inform consumers?

Yes. You can submit in the Safety Business Gateway information that is meant to alert consumers (e.g., a product safety recall notice). The relevant national authority will inspect the submitted information and, if it fulfils the criteria, will create a notification in the Safety Gate Rapid Alert System based on the Safety Business Gateway case. The public information will then be made available to consumers on the Safety Gate Portal. However, this does not replace your obligation to directly reach out to consumers and to disseminate the information widely, where relevant.

3.4.4. Substantial modification

It is essential that products remain safe throughout their lifespan.

Modification of a product, by physical or digital means, might affect the nature and characteristics of the product in a way which was not foreseen in the initial risk assessment of the product, and which might jeopardise its safety. Such modification **by any natural or legal person** should therefore be considered as a substantial modification and, when not done by the consumer or on his behalf, should lead to the **product being considered as a new product from a different manufacturer**.

In order to ensure compliance with the general safety requirement laid down in this Regulation, the person that carries out that substantial modification is considered as the manufacturer and subject to the same obligations. That requirement should only apply in respect **to the modified part of the product, provided that the modification does not affect the product as a whole**. In order to avoid an unnecessary and disproportionate burden, the person carrying out the substantial modification should not be required to repeat tests and produce new documentation in relation to aspects of the product that are not affected by the modification.

It should be up to the person that carries out the substantial modification to demonstrate that the modification does not affect the product as a whole.

Please also be aware that if you **rebrand products and place them on the market under your name**, you **are considered to be the manufacturer of that product**, and you must bear all the responsibilities of a manufacturer.

3.4.5. Cooperation with market surveillance authorities

Economic operators are required to thoroughly cooperate with market surveillance authorities and to provide them with requested information. This cooperation includes **the supply by the economic operators of the following information when requested by the market surveillance authorities**:

For a period of 10 years:

- Full description of the risks presented by the product;
- Complaints related to the products;
- Known accidents; and
- Description of the corrective measures taken to address certain risks.

For a period of 6 years:

- Traceability information regarding suppliers who supplied the product, or a part, a component or any software embedded into the product; and
- Traceability information regarding economic operators to whom the product was supplied.

Furthermore, economic operators might be required to provide regular progress reports on corrective measures to market surveillance authorities.

4. Where can I find more information?

You can find more information on **product safety** on the Safety Gate Portal[35] and the Commission's public website. [36] On these pages, you will find general information about Consumer product safety, as well as information about the Safety Gate, the General Product Safety Regulation, the Product Safety Pledge+, international cooperation on product safety, standards and market surveillance.

The **Blue Guide on the implementation of EU product rules** (the 2022 version is the latest version) [37] provides useful information for businesses. It provides a comprehensive description of the EU laws regulating products and of the context within which the GPSR applies. In particular, the Blue Guide explains (in Sections 1.2-1.3) the difference between harmonised and non-harmonised products from a product safety perspective, when it comes to the presumption of safety, market surveillance and obligations of economic operators. The functioning of the market surveillance in the EU is also further explained (in Section 7).

As concerns the role of economic operators as provided for in Article 4 of Regulation 2019/1020 ('responsible person in the EU'), the Commission has adopted **Guidelines**. [38] Those Guidelines assist both economic operators and supervisory authorities in the uniform application of the provisions of Article 4 of Regulation 2019/1020.

EU Safety Gate Portal

Every day, national authorities send information concerning measures taken or ordered against dangerous non-food products to the Safety Gate Rapid Alert System. Each alert contains information on the product detected as dangerous, a description of the risk and the measures taken by the economic operator or ordered by the authority.

You can find the most recent Safety Gate alerts on the **Safety Gate Portal** [39], as well as the weekly reports [40], and can search for any alert published since 2005 [41]. You can also subscribe to the Safety Gate newsletter [42] to receive the full weekly list of most recently published alerts.

The Safety Gate Portal also provides a link to the **Safety Business Gateway**, where economic operators submit notifications of dangerous products to market surveillance authorities as well as guidelines for the practical implementation of the Safety Business Gateway.

The Safety Gate Portal further **contains a list of relevant contacts** of market surveillance authorities, which deal with dangerous non-food products in the Member States.

[35] https://ec.europa.eu/safety-gate/#/screen/pages/obligationsForBusinesses.

[36] https://commission.europa.eu/business-economy-euro/doing-business-eu/eu-product-safety-and-labelling_en.

[37] Blue Guide on the implementation of the product rules 2022 (OJ C 247, 29.6.2022, p. 1–152).

[38] Commission Notice Guidelines for economic operators and market surveillance authorities on the practical implementation of Article 4 of Regulation (EU) 2019/1020 on market surveillance and compliance of products (OJ C 100, 23.3.2021, p. 1–15).

[39] https://ec.europa.eu/safety-gate-alerts/screen/webReport#recentAlerts.

[40] https://ec.europa.eu/safety-gate-alerts/screen/webReport#weeklyReports.

[41] https://ec.europa.eu/safety-gate-alerts/screen/search?resetSearch=true.

[42] https://ec.europa.eu/safety-gate-alerts/screen/webReport/subscription.

The implementing and delegated measures accompanying the GPSR also provide further information, notably on:

- the **rules on access to and operation of the Safety Gate Rapid Alert System, information to be entered in that System, notification requirements and the criteria for assessment of the level of risk** [(43)];
- the **implementation of the interoperable interface of the Safety Gate Portal for providers of online marketplaces** [(44)] ;
- the **template for a recall notice** [(45)] ;
- the **modalities for consumers and other interested parties to inform the Commission of products that might present a risk to the health and safety of consumers** [(46)] ;
- the **output indicators** [(47)] ; and
- the **roles and tasks of the single national contact points of the Safety Gate Rapid Alert System** [(48)].

Finally, activity reports (including test results) are published in the framework of the regularly organised **Coordinated Activities of the Safety of Products (CASP)**, in the course of which EU and EFTA authorities test together specific products. You can also find **informative factsheets with key messages for businesses** that can help you to acquire information on several product categories. Final reports and information material are available in all EU languages on the Safety Gate Portal [(49)].

[(43)] Commission Delegated Regulation (EU) 2024/3173 of 27 August 2024 supplementing Regulation (EU) 2023/988 of the European Parliament and of the Council with regard to rules on access to and operation of the Safety Gate Rapid Alert System, information to be entered in that System, notification requirements and the criteria for assessment of the level of risk (OJ L, 2024/3173, 13.12.2024).

[(44)] Commission Implementing Regulation (EU) 2024/1459 of 27 May 2024 laying down rules for the application of Regulation (EU) 2023/988 of the European Parliament and of the Council as regards the implementation of the interoperable interface of the Safety Gate Portal for providers of online marketplaces (OJ L, 2024/1459, 28.5.2024).

[(45)] Commission Implementing Regulation (EU) 2024/1435 of 24 May 2024 laying down rules for the application of Regulation (EU) 2023/988 of the European Parliament and of the Council as regards establishing the template for a recall notice (OJ L, 2024/1435, 27.5.2024).

[(46)] Commission Implementing Regulation (EU) 2024/1740 of 21 June 2024 laying down the rules for the application of Regulation (EU) 2023/988 of the European Parliament and of the Council as regards the modalities for consumers and other interested parties to inform the Commission of products that might present a risk to the health and safety of consumers and for the transmission of such information to the national authorities concerned (OJ L, 2024/1740, 24.6.2024).

[(47)] Commission Implementing Regulation (EU) 2024/2958 of 29 November 2024 determining the output indicators relevant for Regulation (EU) 2023/988 of the European Parliament and of the Council on general product safety (OJ L, 2024/2958, 2.12.2024).

[(48)] Commission Implementing Regulation (EU) 2024/2639 of 9 October 2024 laying down rules for the application of Regulation (EU) 2023/988 of the European Parliament and of the Council as regards the roles and tasks of the single national contact points of the Safety Gate Rapid Alert System (OJ L, 2024/2639, 10.10.2024).

[(49)] https://ec.europa.eu/safety-gate/#/screen/pages/casp.

5. Conclusion

The GPSR ensures the safety of products and the protection of consumers. It complements the specific requirements imposed by Union product harmonisation legislation and more generally by Union law. For businesses, it clarifies and harmonises their responsibilities related to product safety and therefore provides higher legal certainty.

Complying with the product safety obligations under the GPSR is important in order to ensure a level-playing field for businesses active in the EU's Single Market and ensure a high level of consumer protection. Businesses that do not comply with their obligations, can be subject to fines imposed by Member States.

It is important to underline that the GPSR itself is not regulating liability rules. You can find out more on **EU product liability legislation** on the Commission's website [(50)].

It is also important to underline the point that legislative requirements can be very significantly complemented by **voluntary initiatives that further enhance product safety**, and recognise the efforts made (e.g., the Product Safety Pledge+ [(51)] or the Product Safety Award) [(52)].

The GPSR also recognises the importance of such voluntary schemes, which go beyond the legal requirements, and gives national competent authorities and the Commission the option of promoting voluntary **memoranda of understanding** with economic operators or providers of online marketplaces, as well as with organisations representing consumers or economic operators, containing voluntary commitments to enhance product safety. All relevant actors are encouraged to develop such initiatives.

Contacts

For other specific questions you might have, you may find further contacts of national market surveillance authorities on the Safety Gate Portal [(53)].

[(50)] https://single-market-economy.ec.europa.eu/single-market/goods/free-movement-sectors/liability-defective-products_en

[(51)] https://ec.europa.eu/safety-gate/#/screen/pages/productSafetyPledge

[(52)] https://ec.europa.eu/safety-gate/#/screen/pages/safetyAward

[(53)] https://ec.europa.eu/safety-gate/#/screen/pages/contacts