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Regulation (EU) 2023/988 on general product safety: An overview of key developments

Regulation (EU) 2023/988 on General Product Safety (GPSR) entered into force on December 14, 2024. This new legal framework aims to strengthen consumer protection against growing risks associated with digitalization, new technologies, and the globalization of supply chains.

It introduces new obligations for economic operators and providers of online marketplaces while clarifying market surveillance mechanisms and the powers of national authorities.

Key Takeaways:

Objective: Ensuring safer products and a high level of consumer protection within the European Union.

Scope: The GPSR applies to new, used, repaired, or reconditioned products available in the EU that are not covered by other specific EU legislation. It excludes some products, such as medicinal products, food and feed, and plant protection products.

General Safety Requirement: The GPSR establishes a general safety requirement. Economic operators must place or make available on the EU market only "safe" products. This requires a risk assessment considering all relevant aspects of the product.

Main obligations of Economic Operators:

Note: Economic operators established outside the EU must appoint a "responsible person for products placed on the Union market".

Manufacturers: Design and manufacture safe products, conduct internal risk assessment, prepare technical documentation, ensure proper traceability, and provide clear safety instructions.

Importers: Ensure imported products comply with the GPSR, verify technical documentation, and include their contact details on the product or packaging.

Distributors: Verify product compliance by checking for markings and required documentation.

Obligations of Online Marketplaces: Appoint points of contact authorities and the public, act swiftly and proactively to remove or disable offers of dangerous products, and cooperate with authorities to eliminate risks.

Market Surveillance: Market surveillance authorities monitor product compliance, conduct inspections, implement corrective measures, and cooperate with each other and the European Commission through information-sharing tools such as the Safety Gate rapid alert system.

The GPSR[1] outlines the new general framework for the safety of non-food consumer products in the European Union (EU), thereby addressing gaps and complementing existing EU sectoral safety regulations.

As such, it is intended to serve as a "safety net", covering products, aspects and risks not addressed by EU harmonization legislation.

The GPSR provides for new product safety rules better adapted to past and future consumer patterns, and strengthens responsibilities across the supply chain to offer equal conditions for all businesses active in the EU.

The GPSR imposes a general safety requirement, ensuring that all products on the EU market are safe and secure for consumers.

All businesses involved in the supply chain, including providers of online marketplaces, play a role in ensuring product safety, and must fulfil specific obligations.

Scope of application

The GPSR applies to new, used, repaired, or reconditioned products available for distribution, consumption or use in the EU, whether for free or against payment, which are not covered by other specific EU product safety legislation. It does not apply to products to be repaired or reconditioned prior to being used where those

products are placed or made available on the market and are clearly marked as such.

As such, it covers products that are tangible, non-tangible or of mixed nature, including apps and software products, and excludes certain products and product groups such as medicinal products for human or veterinary use, food and feed, plant protection products and antiques.

The GPSR does not apply to services, but it does cover products provided to consumers as part of the provision of a service.

The GPSR covers product safety for all types of sale channels, including online sales and other types of distance sales.

Where products are subject to specific safety requirements imposed by Union law, this Regulation applies only to those aspects and risks or categories of risks which are not covered by those requirements.

General safety requirement

The general safety requirement imposed by the GPSR means that economic operators must place or make available on the EU market only safe products[3]. The term "economic operator" includes manufacturers, authorized representatives, importers, distributors, fulfilment service providers or any other natural or legal person who is subject to obligations in relation to the manufacture of products or making them available on the market in accordance with the GPSR.

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

To meet this general safety requirement, the product must undergo a risk assessment, taking into account all relevant aspects of the product, including, but not limited to:

- The characteristics of the product, including its design, technical features, composition, packaging, instructions for assembly and, where applicable, for installation, use and maintenance;
- The effect on other products, where it is reasonably foreseeable that the product will be used with other products, and the effect that other products might have on the product to be assessed, where it is reasonably foreseeable that other products will be used with that product;
- The presentation of the product, the labelling, any warning and instruction for its safe use and disposal, and any other indication or information regarding the product;
- The categories of consumers using the product, in particular by assessing the risk for vulnerable consumers such as children, older people and persons with disabilities;

- The appearance of the product where it is likely to lead consumers to use the product in a way different to what it was designed for;
- When required by the nature of the product, the appropriate cybersecurity features necessary to protect the product against external influences, including malicious third parties, as well as the evolving, learning and predictive functionalities of the product.

It is important to note that the GPSR applies to all kinds of potential health hazards, including mental health risks. It also addresses environmental risks if these pose a threat to consumer health and safety.

The GPSR introduces a presumption of conformity with the general safety requirement when a product is in conformity with relevant European standards referenced in the Official Journal of the European Union.

Other elements can be taken into account for assessing the safety of a product, such as national and international standards, voluntary certification schemes, the state of the art and technology, including the opinion of recognized scientific bodies and expert committees, good-practice codes, reasonable consumer expectations, etc.[4]

Main obligations of economic operators

First and foremost, it should be noted that a product covered by the GPSR may not be placed on the market unless there is an economic operator established in the EU who is responsible for the tasks set out in Article 4(3) of Regulation (EU) 2019/1020[5].

As such, economic operators established outside the EU must appoint a "responsible person for products placed on the Union market"[6] established within the Union for each product falling within the scope of the GPSR. This "responsible person" will serve as the main point of contact for market surveillance authorities regarding any questions related to product compliance.

All actors in the supply chain have obligations related to product safety.

The GPSR specifies obligations incumbent to each of these actors.

Manufacturers

Pursuant to Article 3 of the GPSR, the term "manufacturer" means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under that person's name or trademark.

To ensure compliance with the general safety requirement provided for in the GPSR, manufacturers are subject to several obligations[7], in particular regarding product design and identification, identification of the responsible person, and the provision of safety instructions that can be easily understood by consumers. They must therefore:

- Ensure that the products they place on the market have been designed and manufactured in accordance with the general safety requirement;
- Carry out, before placing their products on the market, an internal risk analysis and draw up and keep up to date a technical documentation containing at least a general description of the product and its essential characteristics relevant for assessing its safety, and keep that documentation at the disposal of the market surveillance authorities;
- Ensure that their products bear a type, batch or serial number or other element enabling the identification of the product and 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;
- Indicate their name, their registered trade name or registered trade mark, their postal and electronic address and, where different, the postal or electronic address of the single contact point at which they can be contacted. That information must be placed on the product or, where that is not possible, on its packaging or in a document accompanying the product;
- Ensure that their product is accompanied by clear instructions and safety information in a language which can be easily understood by consumers.

Where a manufacturer considers or has reason to believe that a product which it has placed on the market is a dangerous product, it must immediately follow a specific procedure which includes *inter alia* taking the corrective measures necessary to bring in an effective manner the product into conformity, including a withdrawal or recall, informing consumers and the market surveillance authorities of the risk to the health and safety of consumers, of any corrective measure already taken, and, if available, of the quantity, by Member State, of products still circulating on the market.

Lastly, manufacturers must make publicly available communication channels (telephone number, electronic address, dedicated section of their website, etc.) enabling consumers to submit complaints and to inform manufacturers of any accident or safety issue they have experienced with a product.

They must investigate complaints submitted, and information received on accidents, that concern the safety of products they made available on the market and which have been alleged to be dangerous by the complainant, and must keep an internal register of those complaints as well as of product recalls and any corrective measures taken to bring the product into conformity.

Authorized representatives

A manufacturer may, by means of a written mandate, appoint an authorized representative[8].

The authorized representative must perform the tasks specified in the mandate received from the manufacturer, including at least being able to provide a market surveillance authority with all information and documentation necessary to demonstrate the safety of the product, informing the manufacturer if it considers

that a product is dangerous, informing and cooperating with the competent national authorities about any action taken to eliminate the risks posed by products covered by its mandate.

Importers

Pursuant to Article 3 of the GPSR, the term "importer" means any natural or legal person established within the EU who places a product from a third country on the EU market.

The primary obligation of importers is to ensure that the product placed on the market complies with the general safety requirement and that the manufacturer has duly fulfilled its obligations.

In this respect, they must, in particular:

- Ensure that the manufacturer has complied with its obligations regarding internal risk analysis, preparation of technical documentation, product identification, and identification of the responsible person for the product;
- Refrain from placing the product on the market if they consider or have reason to believe that the product is not safe within the meaning of the GPSR;
- indicate on the product or, where that is not possible, on its packaging or in a document accompanying the product, their name, their registered trade name or registered trade mark, their postal and electronic address and, ensure that any additional label does not obscure any information required by EU law on the label provided by the manufacturer;
- ensure that the product they imported is accompanied by clear instructions and safety information in a language which can be easily understood by consumers;
- ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardize its conformity with the general safety requirement and the requirements concerning product identification, and identification of the responsible person for the product;
- keep a copy of the manufacturer's technical documentation at the disposal of the market surveillance authorities;
- cooperate with market surveillance authorities and the manufacturer to ensure that a product is safe.

Where an importer considers or has reason to believe that a product which it has placed on the market is a dangerous product, it must immediately inform the manufacturer thereof, ensure that the corrective measures necessary to bring in an effective manner the product into conformity are taken and, where such measures have not been taken, immediately take them. The importer must ensure that consumers and the market surveillance authorities of the Member States in which the product has been made available are immediately informed thereof.

Lastly, importers must verify whether communication channels are publicly available to consumers, and, if not,

provide for them. Importers must investigate complaints submitted and information received on accidents that concern the safety of products they made available on the market, file those complaints, as well as record product recalls and any corrective measures taken to bring the product into conformity in the manufacturer's register or in their own internal register.

Distributors

Pursuant to Article 3 of the GPSR, the term "distributor" means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market.

Distributors must verify that the manufacturer and, where applicable, the importer of the product to be made available on the market comply with their obligations, in particular regarding product identification, identification of the responsible person for the product, and the provision of clear safety information in a language which can be easily understood by consumers.

When a distributor considers that a product does not meet the requirements of the GPSR, it must refrain from making that product available on the market.

Distributors must also ensure that the storage or transport conditions of products under their responsibility do not compromise their safety.

Lastly, where a distributor considers or has reason to believe that a product which it has placed on the market is a dangerous product, it must immediately inform the manufacturer or the importer, as applicable, and the market surveillance authorities thereof, and ensure that the corrective measures necessary to bring in an effective manner the product into conformity are taken.

Obligations common to all economic operators

All economic operators must have internal processes for product safety in place, allowing them to comply with the relevant requirements of the GPSR[9].

They also have the obligation to cooperate with market surveillance authorities regarding actions which could eliminate or mitigate risks that are presented by the products which they made available on the market[10].

In this context, market surveillance authorities may require economic operators to provide:

- specific information about the product (full description of the risk presented by the product, related complaints and known accidents, and corrective measures taken to address the risks) for a period of 10 years after they have been supplied with the product or after they have supplied the product, as applicable; and
- relevant supply chain traceability information about the product, i.e. information about "any economic operator who has supplied them with the product, or with a part, a component or any software embedded into the product" and "any economic operator to whom they have supplied the product", for

a period of six years after they have been supplied with the product, or with a part, a component or any software embedded into the product, or after they have supplied the product, as applicable.

For certain products, categories, or groups of products which are likely to present a serious risk to the health and safety of consumers, the European Commission may, under certain conditions, establish a traceability system involving the collection and retention of data, to which the economic operators that place and make available those products on the market must adhere[11].

Where economic operators make products available on the market online or through other means of distance sales[12], the offer of those products must clearly and visibly indicate mandatory information such as the name, registered trade name, postal and electronic address of the manufacturer, or where applicable, of the responsible person, information allowing the identification of the product, including a picture of it, and any warning or safety information to be affixed to the product or to the packaging or included in an accompanying document.

Economic operators must notify without undy delay accidents related to the safety of products[13].

Specific obligations of providers of online marketplaces in terms of product safety

Pursuant to Article 3 of the GPSR, the term "provider of an online marketplace" means a provider of an intermediary service using an online interface which allows consumers to conclude distance contracts with traders for the sale of products.

It is noteworthy that the GPSR devotes an entire chapter (Chapter IV) to the issue of providers of online marketplaces.

Providers of online marketplaces now have specific obligations to ensure the safety of products placed on the market through their platform, including[14]:

- Designating two single points of contact dedicated to product safety issues: (i) one for market surveillance authorities, through their registration on the Safety Gate portal, and (ii) the other for the public, to enable consumers to communicate directly and promptly with them on these issues;
- Implementing internal processes for product safety to comply without undue delay with the relevant requirements of the GPSR;
- Removing content referring to an offer of a dangerous product from their online interface, disabling
 access to it or displaying an explicit warning, withing 2 working days from receipt of an order from
 market surveillance authorities;
- Taking into account regular information on dangerous products notified by market surveillance authorities via the Safety Gate portal, in order to detect, identify, remove or disable access to content referring to offers of dangerous products on their online marketplace;

- Processing, within a maximum of 3 working days, notices related to product safety issues received through the notification system established under Regulation (EU) 2022/2065[15];
- Designing and organizing their online interface in a way (i) that enables traders offering the product to provide at least the required information (identity and contact details of the manufacturer or, as the case may be, the responsible person, identification of the product, warning or safety information, etc.) for each product offered, and (ii) that ensures that the information is displayed or otherwise made easily accessible by consumers on the product listing;
- Suspending, for a reasonable period of time and after having issued a prior warning, the provision of their services to traders that frequently offer products which are non-compliant with the GPSR;
- Cooperating with the market surveillance authorities, with traders and with relevant economic operators to facilitate any action taken to eliminate or to mitigate the risks presented by a product that is or was offered online through their services (information to consumers, safety warning, withdrawal, recall, notification of accidents, etc.).

Enhanced market surveillance through the development of a rapid information exchange system

Market surveillance is governed by Regulation (EU) 2019/1020[16], some provisions of which apply to products covered by GPSR[17].

As such, market surveillance authorities of the Members States are responsible for carrying out market surveillance to ensure that products on the market conform to applicable laws and regulations and to existing EU health and safety requirements.

They are also responsible for taking the appropriate measures if they find a dangerous product. They collect samples to inspect from both physical shops and the online market and, if necessary, test these samples in specialized laboratories.

Depending on the risk identified, market surveillance authorities can take or impose different types of measures, such as informing customs to reject products at the border, ordering a product recall or the withdrawal of the product, imposing sales bans and/or circulating warning messages.

Where a dangerous product has been identified, market surveillance authorities may also now request from the manufacturer information on other products, produced using the same procedure, containing the same components or being part of the same production batch, which are affected by the same risk.

The European Commission can also take EU action against products posing a serious risk.

It can act, either on its own initiative or at the request of market surveillance authorities, by adopting measures that may include prohibiting, suspending, or restricting the sale of such products, or setting special conditions for testing them or for marketing them.

The European Commission also coordinates joint activities of market surveillance authorities and can, in that context, organize simultaneous coordinated control actions of market surveillance authorities ("sweeps")[18] targeting specific products or product categories where market trends, consumer complaints or other indications suggest that they are often found to present a serious risk.

The strengthening of market surveillance is reflected in the establishment of a rapid information exchange system between the various stakeholders. This system includes several tools:[19]

- The *Safety Gate Rapid Alert System* (formerly RAPEX), which enables the sharing of information on corrective measures taken concerning dangerous products between Member States and the European Commission, and allows for almost immediate notification of products considered to pose a serious risk to consumer health and safety;
- The *Safety Business Gateway*, which enables economic operators and providers of online marketplaces to provide, in an easy way, market surveillance authorities and consumers with information on dangerous products and accidents;
- The *Safety Gate Portal*, which provides the public with free and open access to certain information, and enables consumers and other interested parties to inform the European Commission about products that may pose a risk to consumer health and safety;
- The *Consumer Safety Network*, an administrative cooperation network of Member States' market surveillance authorities, facilitating regular information exchanges on risk assessment, hazardous products, data collection methods, and improving cooperation on the tracing, removal, and recall of dangerous products.

Improved recall process for dangerous products

In case of a product safety recall, or where certain information has to be brought to the attention of consumers to ensure the safe use of a product ("safety warning"), economic operators and providers of online marketplaces must ensure that all affected consumers that can be identified are notified "directly and without undue delay".

Economic operators and, as the case may be, providers of online marketplaces that collect their customers' personal data, including through product registration systems or loyalty programs, may use that information for recalls and safety warnings, provided it is used exclusively for that purpose.

Information on a product safety recall must be provided to consumers in writing and take the form of a recall notice[20].

A recall notice, the headline of which must be "Product safety recall", must include mandatory information such as a clear description of the recalled product, of the hazard associated with the recalled product, of the action consumers should take, etc.

The European Commission has taken the initiative to develop a recall notice template[21] to facilitate the

drafting of such a document.

Where not all of the affected consumers can be contacted directly, economic operators and providers of online marketplaces must disseminate a clear and visible recall notice or safety warning through other appropriate channels, ensuring the widest possible reach including, where available, the company's website, social media channels, newsletters and retail outlets and, as appropriate, announcements in mass media and other communication channels.

Economic operators responsible for a product safety recall must offer the affected consumers an "effective, cost-free and timely remedy" [22], and the 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, provided that the amount of the refund shall be at least equal to the price paid by the consumer.

Penalties

Pursuant to the GPSR, it is up to Member States to set "effective, proportionate and dissuasive" penalties applicable to infringements of the obligations imposed on economic operators and providers of online marketplaces.

In France, pursuant to Article L.452-5-1 of the French Consumer Code, introduced by the DDADUE Law[23], any breach of the obligations arising from the GPSR exposes economic operators and providers of online marketplaces to significant penalties:

- A prison sentence of five years, and
- A fine of €600,000, which may be proportionally increased, in proportion to the benefits derived from the breach, up to 10% of the average annual turnover, based on the last three known annual turnovers at the date of the breach.

In addition, Article L.452-6 of the same Code provides for the prohibition of manufacturers and importers from practicing professional activity in which the breach was committed, for a maximum period of five years.

[1] Regulation (EU) 2023/988 of the European Parliament and of the Council of May 10, 2023 on general product safety

[2] The full list of excluded products is set out in Article 2 of the GPSR

[3] Article 5 of the GPSR [4] Article 8 of the GPSR [5] Regulation (EU) 2019/1020 of the European Parliament and of the Council of June 20, 2019 on market surveillance and compliance of products [6] Article 16 of the GPSR [7] Article 9 of the GPSR [8] Article 10 of the GPSR [9] Article 14 of the GPSR [10] Article 15 of the GPSR [11] Article 18 of the GPSR [12] Article 19 of the GPSR [13] Article 20 of the GPSR [14] Article 22 of the GPSR [15] Regulation (EU) 2022/2065 of the European Parliament and of the Council of October 19, 2022 on a Single Market For Digital Service [16] Regulation (EU) 2019/1020 of the European Parliament and of the Council of June 20, 2019 on market surveillance and compliance of products [17] Article 23 of the GPSR [18] Article 32 of the GPSR [19] Articles 25, 26, 27 and 30 du GPSR [20] Article 36 of the GPSR [21] Commission Implementing Regulation (EU) 2024/1435 of 24 May 2024 [22] Article 37 of the GPSR

[23] Law No. 2024-364 of April 22, 2024, on various provisions for the adaptation of French law to European Union law in matters of economy, finance, ecological transition, criminal law, labor and employment law, and

agriculture

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