THE IMPLEMENTATION OF THE GENERAL PRODUCT SAFETY REGULATION

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Guidance document for the Nonwovens and related Industry

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Contents

Abbreviations

AHP	Absorbent Hygiene Products
CAPA	Corrective and Preventive Action
CPR	Cosmetic Products Regulation
EU	European Union
GPSD	General Product Safety Directive
GPSR	General Product Safety Regulation
ISO	International Organization for Standardization
MDR	Medical Devices Regulation
PLD	Product Liability Directive
SAP	Superabsorbent Polymers

I. INTRODUCTION

EDANA is the leading global association and voice of the nonwovens and related industries.

EDANA Member Companies supply products and services ranging from raw materials to finished products and everything in between including machinery, components and development and testing facilities. It represents not only all types of nonwovens, but also materials often used with nonwovens, such as films and SAP.

Illustrations of some consumers' product supplied by EDANA Member Companies

In May 2023, the European Union adopted Regulation 2023/988[1], which stands as a pivotal component within the European Union's legal framework for product safety, set to replace the existing General Product Safety Directive and the Food Imitating Product Directive on December 13, 2024. This regulation represents a modernization of the broader EU general safety framework.

[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 (Text with EEA relevance)

The aim of the GPSR is to enhance the functioning of the internal market while ensuring a high standard of consumer protection. It establishes fundamental rules concerning the safety of consumer products that are either placed on the market or made available to consumers (GPSR, Art. 1).

Under the GPSR, it is mandated that all consumer products available on the EU market meet safety standards, imposing specific responsibilities on businesses to guarantee compliance. Notably, the GPSR serves as a safety mechanism for products or risks not covered by other EU legislation, ensuring a safety net for European consumers against hazardous products, both presently and in the future.

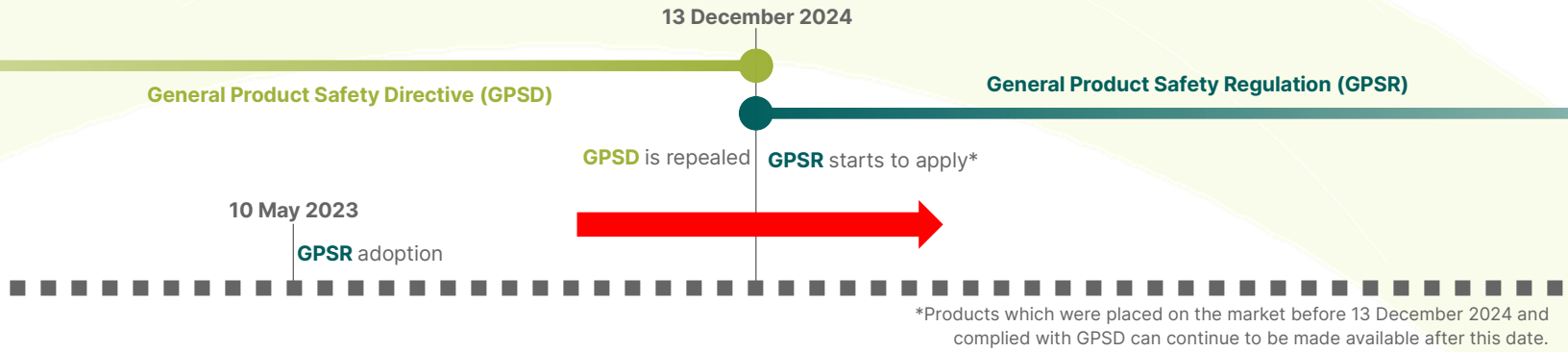
The Regulation introduces several novelties that companies must adapt to before the enforcement of its provisions, starting December 13, 2024. These changes encompass not only the obligations imposed on businesses but also procedural rules and general principles applicable to European institutions and Member States in implementing the Regulation. The latter is also likely to have an indirect impact on businesses, as seen in the overhaul of the standardization process.

The practical application of the Regulation in various aspects calls for guidelines which support Company Members in complying with the requirements of the GPSR.

The GPSR consists of 11 chapters comprising 52 articles, which cover *inter alia* the safety requirements, the obligations of economic operators, the rights of the consumers, and the involvement of EU and national Authorities in the implementation of the Regulation.

These guidelines focus on the obligation of the economic operators, with a special attention to:

- The liability of economic operators along the supply chain
- The relationship between product safety and product liability
- The technical documentation
- The labelling requirements
- The electronic address
- The information to be available in e-commerce direct sales



*Products which were placed on the market before 13 December 2024 and complied with GPSD can continue to be made available after this date.

II. KEY TERMS OF THE GPSR

1. Product: Art. 3(1)

A product is any item, whether or not it is interconnected to other items, supplied or made available, whether for consideration or not, including in the context of providing a service, which is intended for consumers or is likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them.

According to Recital 9 of the GPSR, products which are designed exclusively for professional use, but which have subsequently migrated to the consumer market, are subject to the GPSR because they could pose risks to the health and safety of consumers when used under reasonably foreseeable conditions.

2. Economic operator: Art. 3(13)

An economic operator is either the manufacturer, the authorised representative, the importer, the distributor, the fulfilment service provider or any other natural or legal person who is subject to obligations in relation to the manufacture of products or making them available on the market in accordance with the GPSR.

3. Manufacturer: Art. 3(8)

A manufacturer is 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.

4. Importer: Art. 3(10)

An importer is any natural or legal person established within the Union who places a product from a third country on the Union market.

5. Distributor: Art. 3(11)

A 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.

6. Authorised representative: Art. 3(9)

An authorised representative is any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on its behalf.

7. Making available on the market: Art. 3(6)

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.

8. Placing on the market: Art. 3(7)

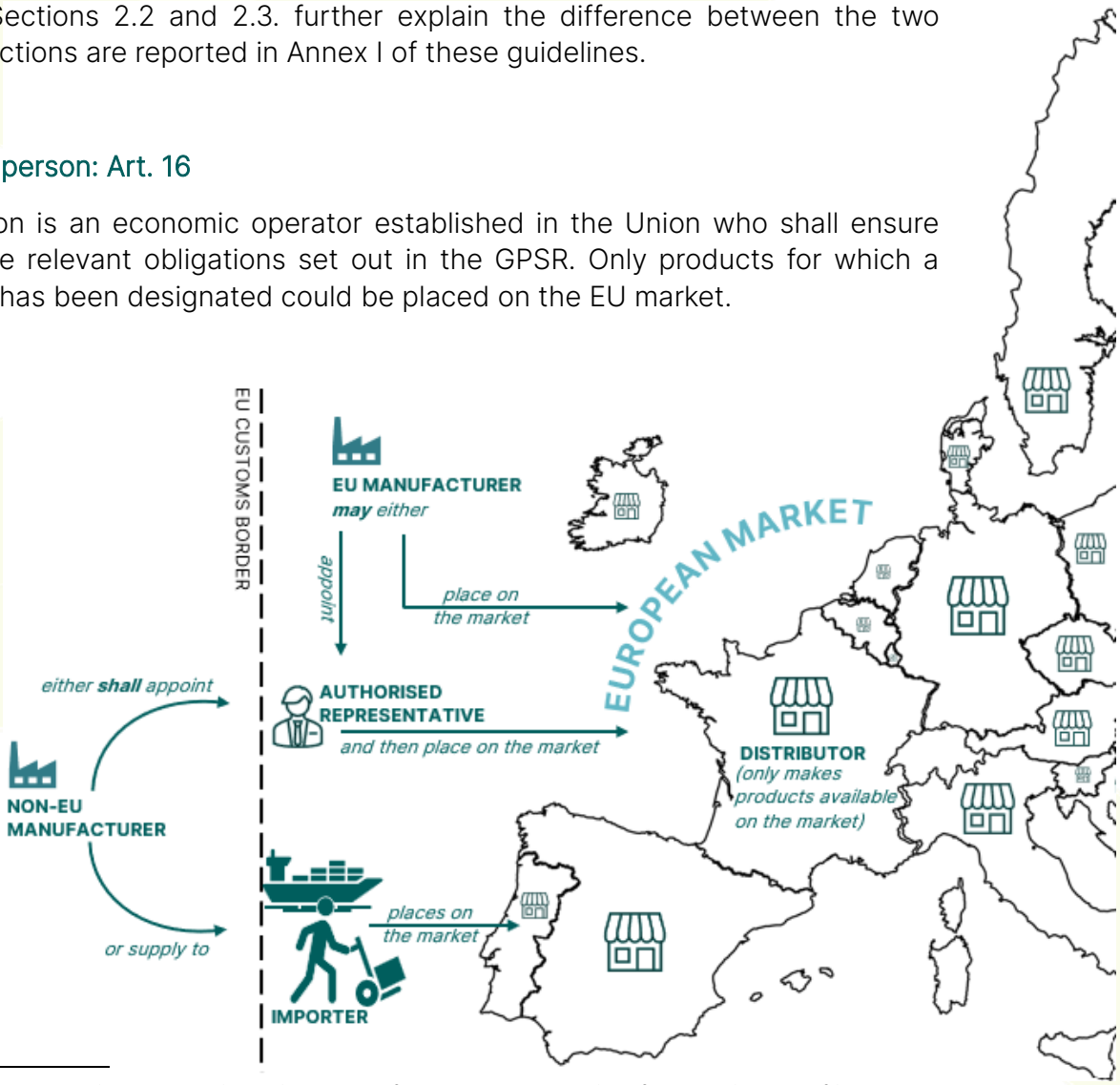
Placing on the market means the first making available of a product on the Union market.

The Blue Guide[2], Sections 2.2 and 2.3. further explain the difference between the two concepts. These sections are reported in Annex I of these guidelines.

9. Responsible person: Art. 16

A responsible person is an economic operator established in the Union who shall ensure compliance with the relevant obligations set out in the GPSR. Only products for which a responsible person has been designated could be placed on the EU market.

Illustrations of the various economic operators involved by the GPSR and their relationships



[2] The current version of the Blue Guide was published in 2022, before the GPSR came into force. While part of its content might still be relevant for the GPSR, the reader should keep in mind that certain aspects might also be outdated.

III. ALLOCATION OF RESPONSIBILITIES WITHIN THE SUPPLY CHAIN

1. A responsible person for each product

The GPSR requires the designation, within the EU, of a responsible person for each product placed on the EU market. This person (who may be a natural (i.e. an individual) or legal person (i.e. a company)) shall take responsibility to ensure that every product they place on the EU market complies with all the requirements of the GPSR.

By default, the manufacturer established in the EU and the importer are the responsible person for the products they place on the EU market.

However, a manufacturer may, by means of a written mandate, appoint an authorised representative to fulfil some of their obligation (GPSR, Art. 10(1)).

2. Identification of the responsible person on the product label

- The name,
- registered trade name or registered trade mark, and contact details, including
- the postal
- and electronic address[3],

of the responsible person shall be indicated on the product or on its packaging, the parcel or an accompanying document.

3. Who is the responsible person?

a. Manufacturer, Importer or a mandated authorised representative as responsible persons

Please refer to Annexes II and IIII to get the full list of the economic operators' obligations under the GPSR.

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

Article 9 of the GPSR provides the obligations of manufacturers, while Article 11 provides the obligations of importers.

[3] Email or website, see Section IV-8

The manufacturer established within the EU will be the responsible person unless they designate an authorised representative to serve as the responsible person.

Non-European manufacturers are required to appoint an entity responsible to act as their representative for market surveillance authorities and who is entrusted with specific tasks (e.g. regularly check compliance with the technical documentation, product and manufacturer information, instruction and safety information) to ensure that products are safe.

An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The authorised representative shall provide the market surveillance authorities with a copy of that mandate upon request. The mandate shall allow the authorised representative to perform at least the following tasks:

- providing a market surveillance authority, upon that authority's reasoned request, with all information and documentation necessary to demonstrate the safety of the product in an official language which can be understood by that authority;
- where the authorised representative considers or has reason to believe that a product in question is a dangerous product, informing the manufacturer thereof;
- informing the competent national authorities about any action taken to eliminate the risks posed by products covered by their mandate through a notification in the Safety Business Gateway, where the information has not been already provided by the manufacturer or upon instruction of the manufacturer;
- cooperating with the competent national authorities, at their request, on any action taken to eliminate in an effective manner the risks posed by products covered by their mandate.

b. Cases in which obligations of manufacturers apply to other persons

Article 12 of the GPSR provides the obligations of distributors. As they only make products available on the market, they cannot be responsible persons by definition (see Chapter II, Section 9 of these guidelines).

However, there are some cases where an economic operator, such as a retailer[4] which is normally identified as a distributor under the GPSR, will become a manufacturer and therefore the responsible person for a product which is placed on the market (GPSR, Art. 13).

Indeed, the relationships between the manufacturer and the retailer under the GPSR may be compared to the relationships between the Original Equipment Manufacturer (OEM) and the Own-Brand Labeller (OBL) in the commercial practices of the medical sector.

[4] The concept of retailers is not defined under the GPSR. According to the situation, they are considered by the GPSR as manufacturers, distributors, importers…

If a retailer places the product of the manufacturer on the market under its own name or trademark, the retailer shall be considered as the manufacturer.

Similarly, if the retailer substantially modifies the product of the original manufacturer, the retailer shall also be considered as a manufacturer.

Last, if a retailer only modifies parts of the product of the original manufacturer and this retailer does not place the product of the original manufacturer on the market under the name or trademark of the distributor, the retailer shall be subject to the obligations of the manufacturer for the part of the product affected by the modification.

Therefore, the qualification of a retailer as manufacturer triggers the application of the obligations of manufacturers to its own situation. For instance, if the retailer is to be considered a manufacturer:

- for the whole product, the retailer shall verify that they indicated their name, their registered trade name or registered trademark, their postal and electronic address and, where different, the postal or electronic address of the single contact point at which they can be contacted, before making the product available on the market.

- for parts of the product, the retailer and the initial manufacturer shall verify that both of them indicated their name, their registered trade name or registered trademark, their postal and electronic address and, where different, the postal or electronic address of the single contact point at which they can be contacted, before making their product available on the market.

In the AHP industry, it is common for retailers to conclude agreements with manufacturers to have AHP designed and produced and then placed on the market under their own brands.

In this situation, the retailer is considered a manufacturer according to Article 13 of the GPSR, and therefore shall comply with the obligations of this status as detailed in Article 9.

However, the original manufacturer remains the most knowledgeable party to fulfil these obligations, which include, *inter alia*, conducting an internal risk analysis and drafting technical documentation.

As explained in Section III-3-a of these guidelines, the retailer may rely on Article 10 of the GPSR to appoint the original manufacturer as the authorized representative and to mandate them to fulfil the obligations under Article 9.

In this scenario, it is the identification of the retailer, at least, that shall appear on the product[5] notwithstanding the appointment of an authorized representative (see Section III-4).

Please refer to Annexes II and III to get the full list of the manufacturer's obligations under the GPSR.

[5] The identification of the original manufacturer may still appear on the product, but it should be made clear which amongst the various companies identified on the product is the responsible person.

4. Duties of the responsible person

The responsible person shall perform the following tasks:

- Verifying that the technical documentation has been drawn up, ensuring that the technical documentation can be made available to those authorities upon request;

- 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 can be easily understood by that authority;

- When having reason to believe that a product in question presents a risk, informing the market surveillance authorities thereof;

- Cooperating with the market surveillance authorities, including following a reasoned request making sure that the immediate, necessary, corrective action is taken to remedy any case of non-compliance with the requirements set out in the GPSR applicable to the product in question, or, 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 its own initiative, where the responsible person considers or has reason to believe that the product in question presents a risk.

In addition, where appropriate with regard to the possible risks related to a product, the responsible person shall regularly check:

- That the product complies with the technical documentation (see Section IV-7)

- That the product complies with the following requirements:

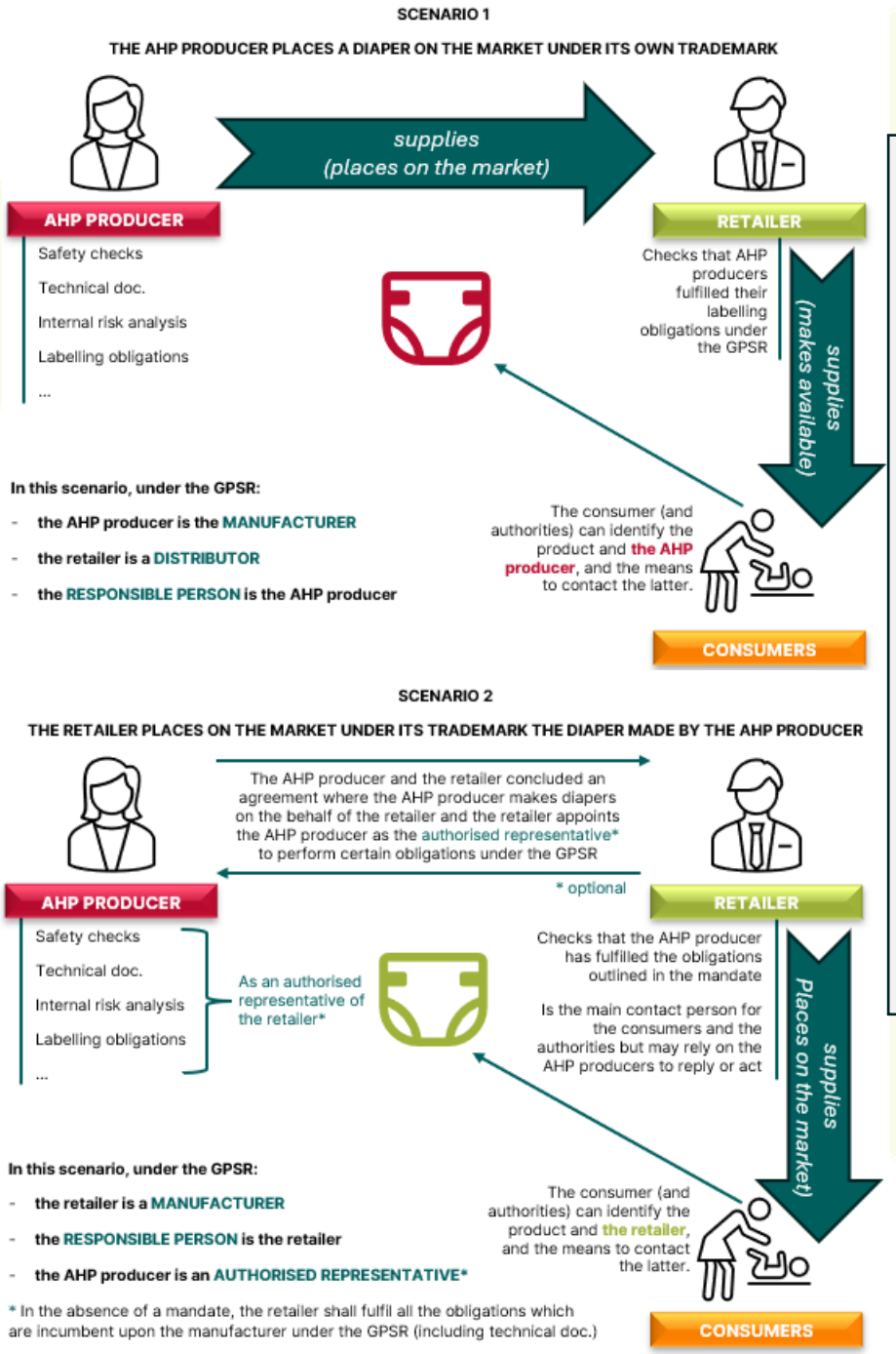
    - The products bear a type, batch or serial number or other element enabling the identification of the product and which is easily visible and legible for consumers, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document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

    - The name of the manufacturer, 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 is indicated. That information shall be placed on the product or, where that is not possible, on its packaging or in a document accompanying the product.

    - The product is accompanied by clear instructions and safety information in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available on the market. That requirement shall not apply where the product can be used safely and as intended by the manufacturer without such instructions and safety information.

The responsible person shall, upon request by the market surveillance authorities, provide documented evidence of the checks performed.

Illustrations of the possible relationships between an AHP producer and a retailer under the GPSR



Good to know!

The GPSR allows economic operators **in addition (not instead)** to make the information, which are required on the label, available in a digital format by means of electronic technical solutions (QR code for instance) clearly visible on the product or, where that is not possible, on its packaging or in a document accompanying the product.

(**GPSR, Art. 21**)

IV. COMPLIANCE WITH THE GPSR

1. Scope of the GPSR

The GPSR is applicable to 'consumer' products, i.e., those intended for use by consumers or might be used by them even if that was not intended by the manufacturer[6]. For products placed or made available on the market subject to sectoral legislation, the GPSR is applicable solely to aspects and risks, or categories of risks, that fall outside the scope of those existing requirements (GPSR, Art. 2(1)).

For instance, the CPR[7] imposes specific safety requirements on cosmetic products and the GPSR applies only to those aspects and risks or categories of risks which are not covered by those requirements. Likewise, chemical and biological risks associated with food contact materials are addressed by Regulation (EC) No 1935/2004[8]; however, physical risks associated with these materials would now fall under the scope of the GPSR.

Aside from this aspect, the GPSR and the CPR provide complementary provisions, such as in the case of online market sales: economic operators making cosmetic products available online shall comply with both Article 19 of the GPSR on the information to be shared with consumers (see Section IV-9 of the guidelines) and Article 19 of the CPR on the labelling requirements for cosmetic products.

Furthermore, the GPSR is not applicable to specific sectors (medicinal products for human or veterinary use, food, feed...) (GPSR, Art. 2(2)).

Last, the GPSR applies to products that are placed or made available on the market, encompassing those that are new, used, repaired, or reconditioned but the Regulation excludes products intended for repair or reconditioning before use, provided they are clearly marked as such when placed or made available on the market (GPSR, Art. 2(3)).

2. Product safety and product liability

Enforcement of safety rules is carried out through market surveillance regulations, which safeguard consumers by preventing the circulation of non-compliant products or by compelling them to meet the required standards. While product safety legislation itself lacks specific clauses addressing business liability, it acknowledges that the PLD[9], soon to be replaced by the New PLD[10], comes into play when a faulty product causes harm. The synergy

[6] Products which are designed exclusively for professional use, but which have subsequently migrated to the consumer market, should be subject to this Regulation because they could pose risks to the health and safety of consumers when used under reasonably foreseeable conditions (GPSR, Recital 9).
[7] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (Text with EEA relevance) Text with EEA relevance
[8] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
[9] Council Directive of 25July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (85/374/EEC)
[10] Proposal for a Directive of the European Parliament and of the Council on liability for defective products (Text with EEA relevance)

between product safety and product liability serves as complementary mechanisms, fostering a functional single market for goods and ensuring elevated safety standards.

3. How to comply with the GPSR?

GPSR comes with clear obligations applicable to all economic operators throughout the supply chain (see Chapter III).

According to Article 14, economic operators shall ensure that they have internal processes for product safety in place, allowing them to comply with the relevant requirements of the GPSR.

Therefore, economic operators must establish operational and regulatory procedures throughout the value chain. These procedures are designed to support and facilitate compliance with the obligations imposed by the GPSR. Examples of such internal processes are risk analysis procedures, CAPA procedures, design validation procedures, considering the intended users and use, complaint systems, procurement procedures and supplier agreements in place.

While the GPSR's scope is theoretically limited to manufacturers directly interacting with consumers, its formulation intends that the entire supply chain ultimately aligns with its provisions, in accordance with market laws.

Key obligations to ensure adherence to the provisions of the GPSR necessitates manufacturers to fulfil stringent obligations such as conducting an internal risk assessment and drawing up a technical documentation regarding the products they place on the market, labelling, notifying the authorities and informing consumers in case of dangerous products.

4. What is a safe product?

Under the GPSR, a "safe product" means 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.

The safety of a product should be assessed by taking into account all relevant aspects of the product, in particular its physical, mechanical and chemical characteristics, and its presentation. The manufacturer needs to take into account the specific needs and risks which the product represents for certain categories of consumers who are likely to use the products, in particular children, older persons and persons with disabilities. Those risks can also include environmental risk, insofar as it poses a risk to the health and safety of consumers.

Products must comply with the general safety requirements. Under the GPSR a product is presumed to be in conformity with the general safety requirement in the following cases (GPSR, Art. 7):

(a) if it conforms to relevant European standards or parts thereof, the references of which have been published in the Official Journal of the European Union[11];

(b) where point (a) above is not applicable, as regards the risks covered by health and safety requirements laid down in the law of the Member State where the product is made available on the market, if it conforms to such national requirements.

Products complying with a standard as listed above, shall be presumed to be safe products so far as it concerns the risks and categories of risk covered by that standard.

Presumption of safety under paragraph above shall not prevent market surveillance authorities from taking action under this Regulation where there is evidence that, despite such conformity, the product is dangerous.

Under Article 8, for the purpose of assessing whether a product is a safe product, and where the presumption of safety under Article 7 does not apply, other elements shall be taken into account, such as International and National Standards and Agreements, and codes of good practice. Therefore, the EDANA Code of Practice for Tampons and the Guidelines on the supply chain information for absorbent hygiene products.

5. Who is the competent authority?

The GPSR regulates the relationships between three main actors: economic operators, consumers, and also the authorities.

The various labelling requirements not only allow consumers to contact operators to exercise their rights under the GPSR, but also help authorities identify products and economic operators, enforce and implement the GPSR, and sanction violators when necessary.

The market surveillance authorities are the authorities designated by each Member State under Article 10 of Regulation (EU) 2019/1020 as responsible for organising and carrying out market surveillance in the territory of that Member State (GPSR, Art. 3(24)).

The exhaustive list of the national authorities competent for market surveillance in different areas may be found on the website of the European Commission.

6. Labelling

Economic operators shall ensure that their products are labelled as follows:

Identifying the product – Manufacturers shall ensure that their product 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, on the packaging or in a document accompanying the product.

[11] in accordance with Article 10(7) of Regulation (EU) 1025/2012

Importers and distributors shall also verify that manufacturers have complied with this obligation before placing or making the product available on the market.

Identifying the manufacturer and the importer – Manufacturers and importers shall 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 trademark,
- their postal address
- their electronic address (see Section IV-8)
- where different, the postal or electronic address of the single contact point at which they can be contacted.

Importers shall verify that manufacturers have complied with this obligation before placing the product on the market and they shall ensure that their additional label does not obscure any information on the label provided by the manufacturer.

Distributors shall also verify that manufacturers and importers have complied with this obligation before making the product available on the market.

Informing the user on the risks posed by a product by providing the necessary user instructions and warnings – Where the product cannot be used safely and as intended by the manufacturer without instructions and safety information, the product shall be accompanied by clear instructions and safety information in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available on the market.

This provision applies to manufacturers and importers.

Distributors shall also verify that manufacturers and importers have complied with this obligation before placing the product on the market.

7. Technical documentation

Manufacturers, importers or any responsible person for products placed on the Union market shall regularly check that the product complies with the technical documentation, keep a copy at the disposal of the market surveillance authorities for a period of 10 years after they have placed the product on the market for the last time and shall ensure that the documents can be made available to those authorities, upon request. The technical documentation should be based on an internal risk analysis carried out by the manufacturer.

The preparation of technical documentation is the manufacturer's responsibility, as is the provision of access to these documents upon request by the Competent Authorities. On their side, the importer/authorised representative shall ensure that the manufacturers have complied with the requirements regarding the technical documentation before placing the product on the market.

Although there are similarities between the requirements of GPSR and product-specific legislation to produce technical documentation providing evidence of conformity with the relevant safety requirements, the content of the technical documentation under the GPSR remains open while sectoral legislation has sometimes detailed requirements (e.g., MDR, Annex II[12] or CPR, Cosmetic Product Safety Report). Recital 33 of the GPSR only provides that the amount of information to be provided in the technical documentation should be proportionate to the complexity of the product and the possible risks identified by the manufacturer.

Based on the above, EDANA Member Companies interpretation of the technical documentation to be drawn up by the manufacturer before the product is placed on the market is that it shall be presented in a clear, organised, readily searchable and should include in particular the following elements:

- a general description of the product enabling its identification (e.g., type, batch or serial number or another element).

- a general description of the essential characteristics of the product, which are relevant to assess its safety (e.g., composition, design, packaging, technical features, mode of action, instructions for use).

- An analysis of risks and adopted solutions to eliminate or mitigate such risks.

  For AHPs, sections 3 and 4 of the AHPs compendium[13] provide useful guidance on the safety evaluation and risk mitigation factors for AHPs.

  Proportionate to the risk and the complexity of the product, the information will be adjusted to include a more extensive description of it. In such cases, an analysis of those risks and the technical means adopted to mitigate or eliminate the risks shall be included.

  Article 6 of the GPSR provides that the following aspects should be taken into account (depending on the product category):

  - the effect on other products, where it is reasonably foreseeable that it will be the case;

  - Interaction with other products, including the effect of non-embedded items that are meant to determine, change or complete the way another product falling under the scope of this Regulation works;

[12] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance) Text with EEA relevance

[13] See EDANA Dossier, Absorbent Hygiene Products (AHPs), A compilation of AHPs key facts with a focus on the Analysis and Risk, Assessment of CODEX TM listed trace chemicals (link)

- the presentation of the product, the labelling, any warnings and instructions for its safe use and disposal, and any other indication or information regarding the product;

- the categories of consumers at risk when using the product, in particular vulnerable consumers such as children, older people and persons with disabilities;

- risk of a product being inadvertently used as a food or toy due to its appearance.

- the fact that although not designed or not intended for use by children, the product resembles an object commonly recognized as appealing to or intended for use by children, because of its design, packaging and characteristics;

- consideration of cybersecurity risks necessary to protect the product against external influences, including malicious third parties, when such an influence might have an impact on the safety of the product;

- the evolving, learning and predictive functionalities of a product.

- A list of standards, or sections of standards or similar, complied with (when applicable). Such standards could be:

  - European standards or other elements applied to meet the general safety requirement laid down in this Regulation. The list of harmonised standards is published on the European Commission's website.

  - When no harmonized standards for the specific product exist to presume conformity with the Regulation safety requirements:

    - National standards.

    - International standards (e.g. ISO standards, ASTM standards).
      Examples in this regard:
      ISO 10377, Consumer product safety – Guidelines for suppliers,
      ISO 10393, Consumer product recall – Guidelines for suppliers.

    - Guidelines documents developed by the European Commission.
      Examples in this regard:

      Guideline for the Notification of Dangerous Consumer Products to the Competent Authorities of the Member States by Producers and Distributors in Accordance with Article 5(3) of Directive 2001/95/EC which assists manufacturers to decide if a specific situation caused by

a product justifies a notification to the competent authorities. This document has a section on how to prepare a risk assessment.

- Safety codes of good practice such as the EDANA Tampon Code of Practice or the EDANA Stewardship Program for AHPs.
- State of the art technologies.
- Reasonable consumer expectations.

- The outcome of relevant tests (e.g. test reports).

When applicable, the manufacturers shall identify the parts of European standards, health and safety requirements or elements listed above which have been only partly applied.

Sections of the technical documentation may be stored in different locations, which are usually controlled by the manufacturer's quality management system, and the responsible person shall have every required information available and ready to be shared upon request of the Authorities. The technical documentation must be kept up to date throughout the marketing of the product line, to ensure it accurately reflects the current status of the product.

8. The definition of electronic address

The GPSR requires the manufacturers and the importers to indicate on the product or, where applicable, on the packaging, their electronic address.

In addition, manufacturers shall make publicly available communication channels such as an electronic address or a dedicated section of their website, enabling consumers to submit complaints and to inform manufacturers of any accident or safety issue they have experienced with a product.

In case of distance sales, the electronic address of the manufacturer or the responsible person shall also be indicated. The objective of the Authorities is to allow consumers to reach out to the responsible economic operator through digital means, the same way they would do through postal means.

The term "electronic address" encompasses both the email address of the responsible economic operator and the URL address of its website, either of which can be used[14].

[14] While it was not clear for a moment whether the intention of the EU legislator was that the term "electronic address" should cover both the notions of "email address" and "website" following the adoption of the GPSR, the EU legislator later shed light on the delineation of the concept.
Indeed, the translation of the GPSR was not homogeneous among the 24 translations of the Regulation in the official languages of the EU: all translations referred to "electronic address", whereas the Spanish, the German, the Estonian, the Croat, the Romanian, and the Finish versions referred to "email address", which is more restrictive.
However, on 19 December 2023, the EU adopted a corrigendum in all six languages to replace "email address" with "electronic address".

9. The information to be available on products offered for sale online or through other means of distance sales

Under Article 4 of the GPSR, products offered for sale online or through other means of distance sales shall be deemed to be made available on the market if the offer is targeted at consumers in the Union.

An offer for sale shall be considered to be targeted at consumers in the Union if the relevant economic operator directs, by any means, its activities to one or more Member States.

Article 19 provides the obligations of economic operators in the case of distance sales.

Where economic operators make products available on the market online or through other means of distance sales, the offer of those products shall clearly and visibly indicate at least the following information:

- name, registered trade name or registered trade mark of the manufacturer, as well as the postal and electronic address at which they can be contacted;
- where the manufacturer is not established in the Union, the name, postal and electronic address of the responsible person;
- 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 to the product or to the packaging or included in an accompanying document in accordance with this Regulation or the applicable Union harmonisation legislation in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available on the market.

In addition to relevant national legislation, economic operators making products available on the market online shall also comply with the relevant EU law regarding e-commerce[15].

[15] Such as Directive 2000/31/EC (E-Commerce Directive), the Consumer Rights Directive (2011/83/EU), the Payment Services Directive 2 (PSD2), the Geo-blocking Regulation (EU) 2018/302, and the Digital Services Act (DSA) and Digital Markets Act (DMA).

V. INSTITUTIONAL PROCEDURE FOR STANDARDISATION: CHANGES BROUGHT BY THE GPSR

Under the GPSR, the Commission will enact implementing measures to specify the safety criteria essential for ensuring that products aligning with European standards meet the overarching safety provision outlined in Article 5. An illustration of this is found in the Commission Decision 2023/1338 dated 28 June 2023[16], which outlines the safety prerequisites that European standards for specific children's products and associated items must fulfil in accordance with Directive 2001/95/EC on general product safety.

Indeed, while 2023 was a transitional year between the GPSD, which will be repealed on 13 December 2024 when the GPSR will start to apply, the European Commission however published on 28 June 2023 a Decision on the safety requirements to be met by European standards for certain children's products with the old (but still in force) GPSD as the legal basis.

Article 3 of the Directive indeed provides that "a product shall be presumed safe as far as the risks and risk categories covered by relevant national standards are concerned when it conforms to voluntary national standards transposing European standards". The European standards are defined thanks to a step-by-step approach, following the procedure detailed in Article 4:

1) The Commission decides on the requirements intended to ensure that products which conform to those standards satisfy the general safety requirement (Art. 4, 1., (a)),
2) The Commission then calls on the European standardisation bodies to draw up standards which satisfy these requirements (Art. 4, 1., (b)),
3) Last, the European standardisation bodies adopt the standards in accordance with the principles contained in the general guidelines for cooperation between the Commission and those bodies (Art. 4, 1., (c)),

With regard to the safety requirements to be met by European standards for certain children's products, we are currently at the first stage of the procedure: the Commission has just decided on the requirements intended to ensure that products which conform to those standards satisfy the general safety requirement.

It should be noted that, under the new GPSR, it will not be necessary anymore to have the European standard transposed into a voluntary national standard for the product to be presumed to be in conformity with the general safety requirement: the presumption will be directly linked to the existence of a European standard, as defined by the European standardisation bodies.

On the question to know how the GPSR prevents an overlap between previous/current European Standards adopted under the GPSD and future European Standards to be adopted under the GPSR, Recital (27) of the new Regulation states that "*European standards, the references of which have been published in accordance with Directive 2001/95/EC, should continue providing a presumption of conformity with the general safety requirement laid*

[16] Commission Decision (EU) 2023/1338 of 28 June 2023 on the safety requirements to be met by European standards for certain children's products and related products pursuant to Directive 2001/95/EC of the European Parliament and of the Council

down in this Regulation. Standardisation requests issued by the Commission in accordance with Directive 2001/95/EC should be deemed to be standardisation requests issued in accordance with this Regulation".

VI. QUESTIONS & ANSWERS

How does the GPSR deal with products placed in stocks before the Regulation starts to apply?

Article 51 provides that Member States shall not impede the making available on the market of products covered by Directive 2001/95/EC which are in conformity with that Directive and which were placed on the market before 13 December 2024.

This means that GPSD compliant products may be sold after the 13th of December 2024 if the following is met prior to the 13th of December 2024:

- The individual product was fully manufactured (i.e., in final product form) in compliance with the GPSD,
- and, either:
  - the product was offered for sale, or
  - the product had a written or verbal agreement to transfer ownership, possession, or any other property right from manufacturer to the distributor, retailer, or customer.

The manufacturer must be able to provide the adequate documentation, justification, and/or traceability to demonstrate that individual products that were manufactured and offered for sale or had agreement prior to the 13th of December 2024.

Regarding individual products manufactured after the 13th of December 2024, they shall be compliant with the GPSR.

Are penalties harmonized or decided by each Member State?

Criminal law is not yet harmonised at the EU level. It remains within the set of competences of the Member States and the EU can only provide a general framework.

In the case of the GPSR, the Member States shall lay down the rules on penalties applicable to infringements of this Regulation that impose obligations on economic operators and providers of online marketplaces and shall take all measures necessary to ensure that they are implemented in accordance with national law.

The penalties provided for shall be effective, proportionate and dissuasive.

The Member States shall, by 13 December 2024, notify the Commission of those rules and of those measures, where they have not previously been notified, and shall notify it, without delay, of any subsequent amendment affecting them.

Article 6(d) requires that when assessing whether a product is a safe product, the labelling, including the labelling regarding age suitability for children shall be taken into account. Which products is it required on? Any specific wording?

Based on the outcome of the risk assessment, economic operators can determine whether the age suitability for children should appear on the label of the product.

Products covered by CE-label: would they be deemed compliant?

The CE-label indicates that the product is in conformity with the relevant regulation (i.e., medical device, PPE, toys).

It cannot be used to assume nor confirm compliance with the GPSR.

Please refer to Article 2(1) of the GPSR to identify which requirements of the GPSR remain applicable even in the situation where the product is subject to specific requirements imposed by an EU legislation dealing with the CE-label.

References

LEGAL AND RELATED ACTS

GPSR - 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 (Text with EEA relevance) →| link

GPSD - Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (Text with EEA relevance) →| link

Blue Guide - Commission notice – The 'Blue Guide' on the implementation of EU product rules 2022 →| link

PLD - Council Directive of 25July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (85/374/EEC) →| link

New PLD - Proposal for a Directive of the European Parliament and of the Council on liability for defective products (Text with EEA relevance) →| link

CPR - Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (Text with EEA relevance)Text with EEA relevance →| link

FCM - Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC →| link

MDR - Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance) Text with EEA relevance →| link

European Standardisation - Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council Text with EEA relevance →| link

INDUSTRY DOCUMENTS

EDANA

- Guidelines on the supply chain information for absorbent hygiene products ⇥ link
- EDANA dossier, Absorbent Hygiene Products (AHPs), A compilation of AHPs key facts with a focus on the Analysis and Risk, Assessment of CODEX TM listed trace chemicals ⇥ link
- EDANA Code of Practice for Tampons ⇥ link