

### EU General Product Safety Regulation GPSR

Regulation (EU) 2023/988 on general product safety

European Commission DG Justice and Consumers Unit B4 "Product Safety & Rapid Alert System"

## **Objectives and scope**



#### Consumer detriment due to unsafe products in the EU





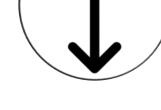
Preventable detriment to consumers & society

EUR 11.5 billion per year

Value of unsafe products

EUR 19.3 billion





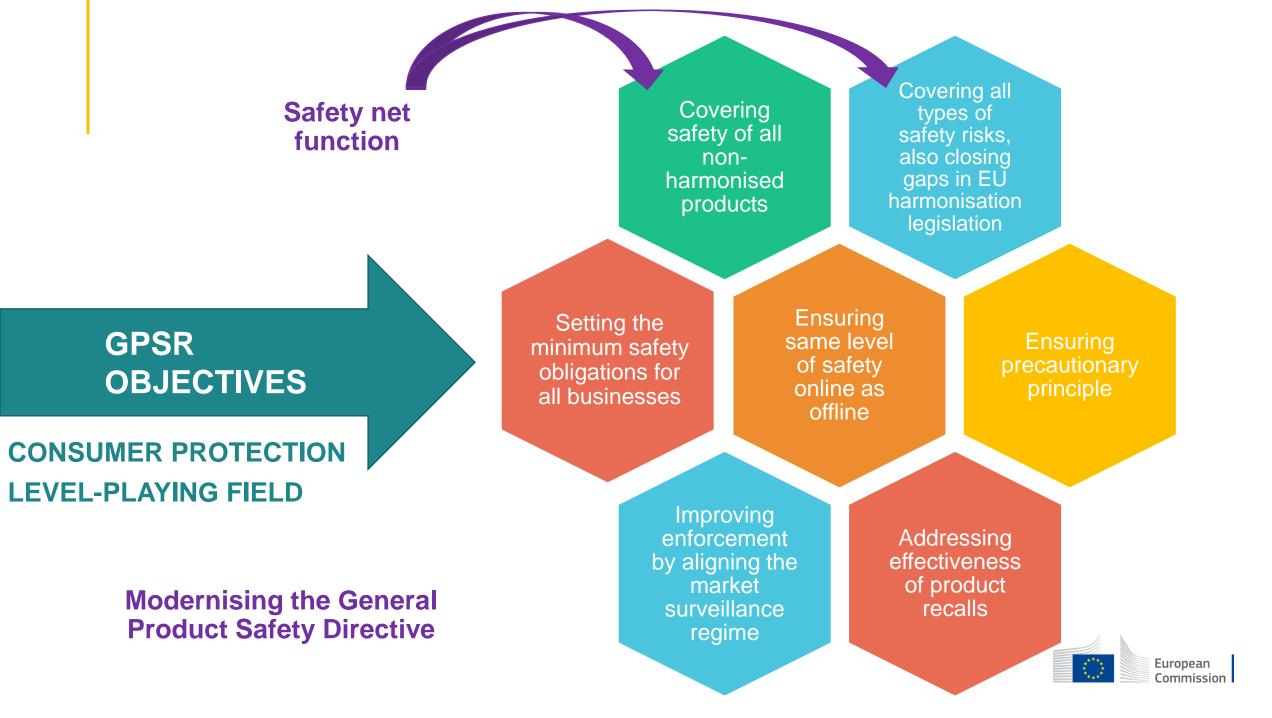


EUR 1 billion in 2025

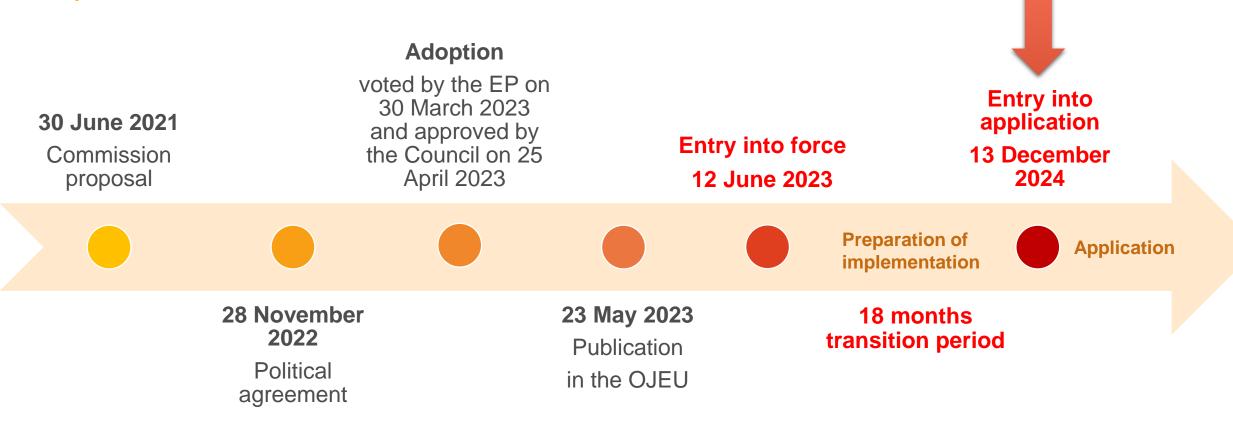
EUR 5.5 billion over the next decade

10





### **GPSR** Timeline





### GPSR subject and scope

The GPSR lays down essential rules on the safety of consumer products placed/made available on the EU market

All businesses that target EU consumers are subject to the obligations

! Both for online (distance) and offline sales !

- GPSR applies to consumer products placed / made available on the EU market:
  - for which no specific safety provisions are provided in other EU legislation and
  - for products subject to specific safety requirements (by Union harmonised legislation), the GPSR applies to aspects and risks not covered by those specific safety requirements

Europear

 GPSR clearly underlines that it applies to all kinds of potential health hazards, including mental health risks

### **Products covered - examples**

New and Second-hand

Reconditioned and refurbished

px Spx #ccc}.gbrtl .gbm{-mozc;display:block;position:abso pacity:1;\*top:-2px;\*left:-5pt 0/;top:-4px\0/;left:-6px\0/;r nline-box;display:inline-block;f c(display:block;list-style:none block;line-height:27px;pad c:z-index:1000}.gbts{\*dic:z-index



### New technology products

GPSR addresses the safety of **new technology products:** 

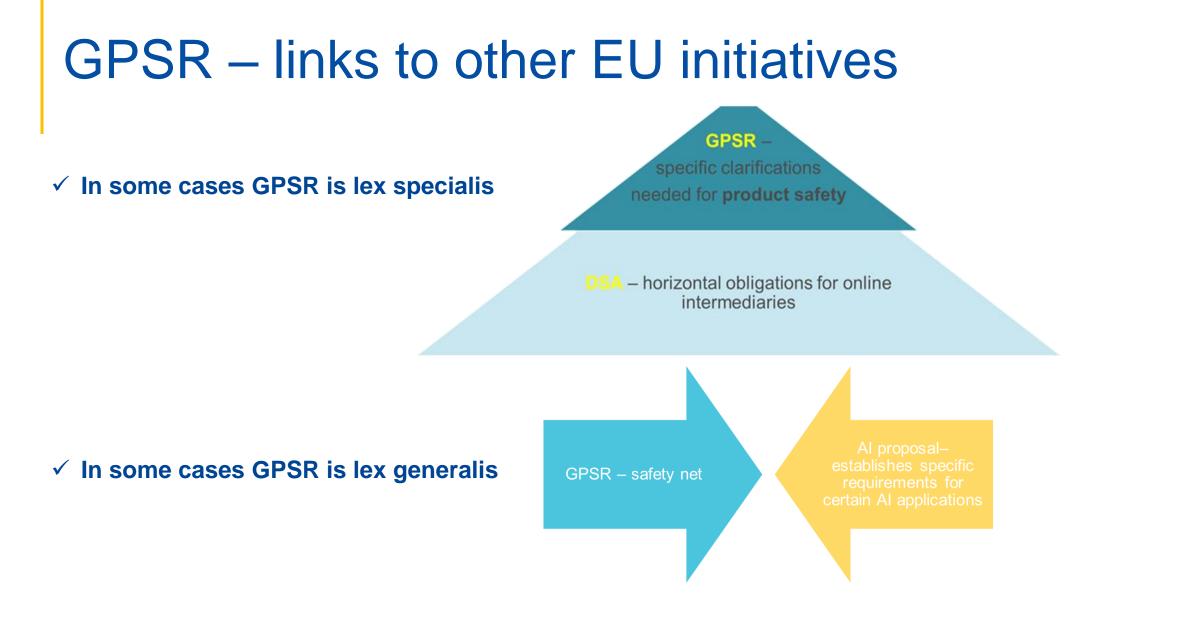
- Coverage of new risks posed by new technologies to consumer's health and safety and personal security risks
  - → the risks and specific features of new technologies are integral part of the risk assessment
- Clarification of **software** related rules (definition of product, risk assessment, substantial modification)



### **Excluded products**







✓ It does not affect directly liability rules (under the Product Liability Directive)



### GPSR - interaction with harmonised legislation

Specific application of the GPSR for harmonised products (listed in Annex I of the Market Surveillance Regulation (EU) 2019/1020):

- Following rules <u>are applicable</u> to harmonised products:
  - ✓ Chapter I (general provisions),
  - Chapter III, Section 2 (obligations of economic operators on accident reporting and distance sales),
  - ✓ Chapter IV (obligations of online marketplaces),
  - ✓ Chapter VI (Safety Gate Rapid Alert System and Safety Business Gateway) and
  - Chapter VIII (Right to information and to a remedy, product recalls, memoranda of understanding, representative actions)
- Chapter II GPSR on safety requirements applies to harmonised products for risks not covered by EU harmonised legislation



GPSR obligations for businesses



### Who is concerned by the GPSR?





**One company** 

### Type of obligations

#### PREVENTION

- Safety by design
- Risk assessment and technical documentation
- Appropriate labelling and traceability systems
- Safety information
- Internal processes for product safety
- Complaints handling
- Responsible person in the EU

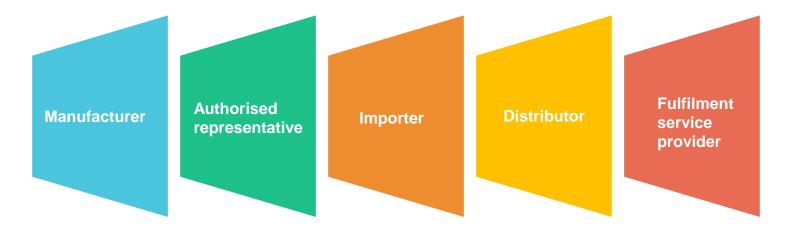
#### CORRECTION

- Corrective actions including recalls
- Alerting about dangerous products
- Cooperation with authorities
- Informing about accidents



### Clear obligations for economic operators

• Introduction of specific product safety obligations for economic operators according to their respective role in the supply chain



- Alignment with rules applicable to harmonised products
- New additional tasks:
  - accident reporting, complaint handling



# The definition of a manufacturer and substantial modification

The GPSR defines 'manufacturer' as the operator who:

manufactures or has a product designed or manufactured **and** it places a product on the market under its name or trademark (article 3)

or places the product on the market under its name or trademark (article 13)

### => White label/ Rebranding/ adding trademark = manufacturer



When an economic operator substantially modifies a product (i.e. where the modification- physical or digital - has an impact on the safety of the product), it will be considered as a manufacturer

=> Certain circular business models (case by case basis)

European Commission



### Manufacturer - essential role in product safety

Manufacturer – safety by design



- Technical documentation is a great tool for manufacturers to prove they did a risk analysis and for authorities to verify whether manufacturers comply with their obligation to perform an internal risk analysis
- **Importers must keep a copy** of the technical documentation for a period **of 10 years** after placing the product on the market, and should make this copy available to the authorities upon request

European Commission

### **Risk analysis**







#### **Characteristics**





**Categories of** consumers



**Effects on other** products, cybersecurity features, evolving functionalities



#### **Appearance**

Child-appealing





**Food-imitating** 

#### **Presentation**



### Risk analysis feeds technical documentation







# Technical documentation under GPSR: for all products

#### **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

Potential risk 1:

Description of potential risk:

Measures to address this potential risk:

- All substances used in the product and packaging comply with [...]

- The [...] complies with European standard [...]
- Warnings and instructions for use provided

Potential risk 2: Description of potential risk: Measures to address this potential risk: [...]

# Use of standards in the GPSR: Presumption of conformity

- Standards cited in the Official Journal of the EU under GPSR give the "presumption of conformity with the general safety requirement" for the risk that they cover.
- $\Rightarrow$  Article 7 of the GPSR
- ⇒ Technical standards help with compliance but remain legally voluntary
- Childcare articles, lighters, bicycles, gym equipment, lighters, laser products, etc.
- Alignment of standardisation procedures to the general regime contained in Regulation (EU) 1025/2012



### Responsible person in the EU: who it is?



### Tasks of the "responsible person"

The responsible person has specific tasks related to product safety:

- Verifying the technical documentation has been drawn up and ensuring it can be made available to authorities upon request
- Providing information and documentation demonstrating product compliance, upon request by authorities
- Informing authorities about dangerous products
- Cooperating with authorities, including ensuring corrective actions
- ✓ Regular compliance checks:
  - ✓ Product complies with technical documentation
  - ✓ Product has correct labelling and safety information, instructions

Same as under Reg (EU) 2019/1020) Additional tasks related to safety under the GPSR European

Commission

### Mandatory product information

On the product if possible by the size

If not, on the packaging or on accompanying doc

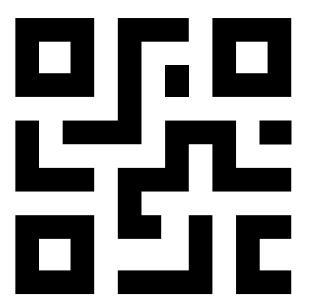
Same product information online as it is with the product offline



Also for harmonised products

#### **PRODUCT OFFER in DISTANCE SALES PHYSICAL PRODUCT** Product identification: Product identification: Type, batch or serial number or other element enabling product identification (e.g. Information allowing the **identification of the product**, including a picture of it, its type and any other product identifier barcode). Manufacturer: Manufacturer: - name, registered trade name or registered trade mark - name, registered trade name or registered trade mark - postal and electronic address and, if different, the postal address or electronic - postal and electronic address at which it can be contacted address of the contact point through which consumers can contact manufacturer Importer: - name, registered trade name or trade mark - postal and electronic address and, if different, the postal address or electronic address of the contact point through which consumers can contact manufacturer where the manufacturer is not established in the Union: **Responsible person in the EU:** Responsible person in the EU within the meaning of Article 16(1) of this Regulation or - name or registered trade mark Article 4(1) of Regulation (EU) 2019/1020: - contact details, including the postal and electronic address - name postal and electronic address any warning or safety information to be affixed to the product or to the packaging or clear instructions and safety information in a language which can be easily included in an accompanying document in accordance with the GPSR or the applicable understood by consumers Union harmonisation legislation in a language which can be easily understood by consumers





## Digital labelling alone is NOT sufficient!



#### Mandatory reporting of accidents and safety issues

Which accidents? When the use of a product resulted in:

- death
- serious adverse effects on the health and safety of a person (such as injuries, other damage to the body, illnesses and chronic health effects), permanent or temporary

#### Who must report?

- 1) the manufacturer;
- 2) the importers and distributors must inform the manufacturer and can be instructed to notify the accident
- 3) if the manufacturer is not in the EU –> responsible person

#### How to report? Via the Safety Business Gateway

 Systematic use of the Safety Business Gateway for accident reporting and reporting of safety issues



### Other obligations for economic operators

### Internal processes to be put in place by all economic operators:

- To ensure compliance with this regulation
- Depending on their role in the supply chain and the type of products concerned
- Examples: organisational procedures, guidelines, standards, ad hoc manager...

#### **Complaint handling by manufacturers and importers:**

- Ensure that consumers can submit complaints and inform them about accidents or safety issues
  - How? Via a telephone number, electronic address or dedicated section of their website
- **Investigate** complaints and keep an internal register of those complaints (personal data to be kept not longer than 5 years)



### Cooperation with authorities

Obligation to cooperate with authorities to eliminate or mitigate risks

Market surveillance authority can ask for:

- A full description of the risk presented by the product, related complaints and known accidents
- A description of any corrective measure taken to address the risk
- Economic operators up and down the supply chain:
  - Who has supplied the product / a part / a component or any software embedded into the product
  - To whom the product has been supplied.



### **Record-keeping**









Information on operators the product has been supplied to

6 years



### Checklist in case of safety issue

#### ✓ Inform consumers

✓ Take corrective measures

✓ Inform Market Surveillance authorities of Member States in which the product has been made available

=> through the Safety Business Gateway

✓ Inform supply chain



### Make product recalls more effective

Businesses: obligation to inform consumers about product safety recalls and safety warnings (Art 35)

Issue 1: Consumers often not aware of recalls affecting them

→ Mandatory requirements to raise consumer awareness:

- direct notification of consumers when possible
- wide dissemination of recall information, including publication of recall notices by online marketplaces
- use of registration schemes
- Issue 2: Consumers not reacting to recalls affecting them

→ Mandatory requirements to increase consumer reaction to recalls:

- key elements for recall notices with template
- right to remedy

	[COMPANY NAME] RECALLS [NAME OF THE PRODUCT]
	[Insert PICTURE OF PRODUCT & graphical indication of where to find identification additers (f applicable)]
<ul> <li>Identification</li> </ul>	T IDENTIFICATION INFORMATION: numbers, such as batch and serial number n where and when product was sold (if available)
	HAZARD
<ul> <li>Don't use any</li> </ul>	he hazard the product poses and why terms or expressions that may decrease consumers' perception of risk, e.g. precautionary", "in rare/specific situations"
	WHAT TO DO
<ul> <li>Clearly explain</li> </ul>	mers to stop using the product immediately n how to participate in the recall (e.g., return to point of sale, schedule for in-house pick-up/repair, etc.)
	REMEDY
Clearly descri	be the remedy available to consumers (e.g., repair, replacement, refund)
	CONTACT
	te and free phone number, interactive online service and/or email address where n get more information
	[APOLOGY (OPTIONAL)]

#### **Recall notice template**

**Product Safety Recall** Date loptiopo [Company name] recalls [product] Insert picture(s) of product and, if applicable, a graphical indication of where to find product identification numbers on the product. For the online version of the recall notice, it is important that essential information contained in the picture, especially if it is needed to identify the recalled product, is also available in a machine-readable format. Include a clear description of the recalled product, including product identification information: Name and brand of the product Product identification numbers, such as batch and serial number, and optionally the barcode or the period of production of the product, and, if applicable, graphical indication of where to find them on the product · Information on where, when and by whom the product was sold, if available Why is this product dangerous? Clearly state the hazard the product poses and why. Do not use any terms or expressions that may decrease consumers' perception of risk, such as 'voluntary', 'precautionary', 'discretionary', 'in rare situations' or 'in specific situations'. Do not indicate that there have been no reported accidents. What to do Clearly indicate what safety precautions consumers should take. This indication shall include an instruction to immediately stop using the recalled product, unless a temporary safe use under certain conditions, which should be specified in the notice for the consumer, is possible. Clearly explain the action(s) consumers should take (for example, return to point of sale, schedule appointment for in-house pick-up/repair, software update...). In case the repair shall be conducted by the consumer itself, please include the instruction in a separate document attached to this recall notice. Remedies for consumers · Clearly describe the remedies available to consumers in accordance with Article 37 of Regulation (EU) 2023/988 (repair, replacement, refund). · Indicate any other remedy or additional incentives, such as discounts or vouchers, if

available.

Spread the word about this recall, especially if you know that the recalled product was offered, lent or sold to someone else

#### **Product Safety Recall**

Date

#### Contact

 Provide the address of an interactive online service (such as a website with a contact form, or an email address) and/or free phone number where consumers can get more information in relevant official language(s) of the Union.

Provide the postal address of the company (optional).

Company logo

#### [Apology (optional)]

[Links to social media post /website informing about the recall (optional)]

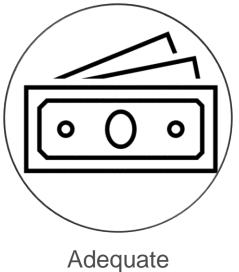
[QR code or other technical solution leading to recall page/more information (optional)]

Spread the word about this recall, especially if you know that the recalled product was offered, lent or sold to someone else



### Remedies in case of product recall

**Provide at least two remedies:** 



Refund



Repair



Replacement



Product safety related obligations of providers of online marketplaces

Chapter IV on product safety obligations of providers of online marketplaces:

- Obligations are linked to the intermediary function of these businesses
- Close interlink and coherence with the Digital Services Act

#### Main obligations (amongst others)

- ✓ Obligation to register in the Safety Gate Portal and indicate the point of single contact
- ✓ Have internal processes for product safety in place in order to comply without undue delay with the relevant requirements of the GPSR
- Follow up on orders within 2 working days at latest (and "staydown")
- ✓ Process **notices** within 3 working days at latest



# Product safety related obligations of providers of online marketplaces

#### Main obligations (amongst others)

- ✓ Design of the interface to ensure display of minimum traceability and safety information by the traders
- ✓ Ex post random checks based on the Safety Gate
- ✓ Measures against repeat offenders
- Cooperation obligations, including on:
  - Recalls
  - Not hindering web scrapping
  - Informing relevant authorities and traders on unsafe products
  - Use of the Safety Business Gateway

Encouragement to go beyond the legal requirements via voluntary cooperation (Product Safety Pledge+, MoU)

## Important to know



### Businesses obligations – Quick Recap



EU products rules apply to **all products** on the EU market, accross **all sales channels**: products manufactured outside the EU and targetting EU consumers **should also comply with EU rules** 

- $\rightarrow$  Products must be safe
- $\rightarrow$  All specific product obligations apply



Products coming from outside the EU and offered to EU consumers must have a **responsible person** in the EU

 → The responsible person has specific tasks related to product safety:
 cooperation obligations and regular compliance checks



If you become aware of any safety issue with your product that is offered to EU consumers:

- report it via the EU Safety Business Gateway
- ensure corrective actions are taken

- Inform consumers
- Inform across the supply chain

Every business has its role in product safety: learn your respective responsibilities





## Where to find more information (1)

#### Safety Gate Portal

https://ec.europa.eu/safety-gate/#/screen/home?lang=en

#### Product safety legislation

https://ec.europa.eu/safety-gate/#/screen/pages/productSafetyLegislation

#### GPSR:

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32023R0988 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=legissum:4670517

#### Information for businesses

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

https://commission.europa.eu/business-economy-euro/doing-business-eu/eu-product-safety-and-labelling/product-safety\_en

#### Technical standards

https://commission.europa.eu/standards-and-risks-specific-products\_en



## Where to find more information (2)

#### Safety Business Gateway

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

#### Safety Gate - Online Marketplace Registration Module

https://ec.europa.eu/safety-gate/Online-Marketplace-Registration/screen/home

#### Member States Market Surveillance Authorities

https://webgate.ec.europa.eu/safety/consumers/consumers\_safety\_gate/menu/documents/Business\_Gateway\_contacts.pdf

#### Alerts on measures taken against dangerous products:

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

#### Consumer Safety Gateway

https://webgate.ec.europa.eu/consumer-safety-gateway/screen/public/home



# Thank you!

