

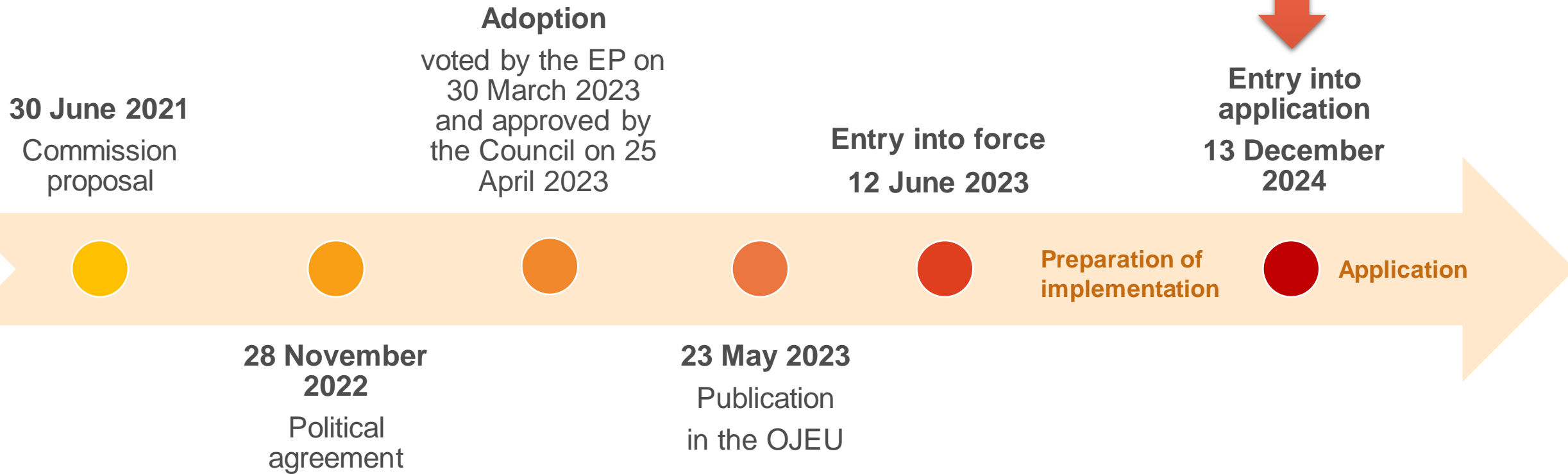


EU General Product Safety Regulation GPSR

Regulation (EU) 2023/988 on general product safety

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

GPSR Timeline



What is the GPSR?

Consumer detriment due to unsafe products in the EU



**Preventable detriment
to consumers &
society**

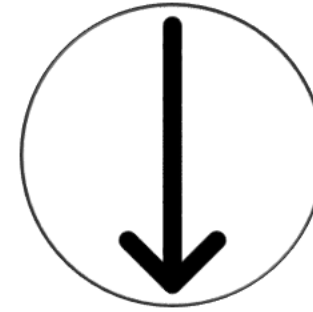
**EUR 11.5 billion per
year**



Value of unsafe
products

EUR 19.3 billion

Reduced
consumer
detriment
by the
GPSR



EUR 1 billion in
2025



EUR 5.5 billion
over the next
decade

GPSR specific OBJECTIVES

Safety net
function

Covering
safety of all
non-
harmonised
products

Covering all
types of
safety risks,
also closing
gaps in EU
harmonisation
legislation

Setting the
minimum safety
obligations for
all businesses

Ensuring
same level
of safety
online as
offline

Introducing
product safety
requirements
for online
marketplaces

Improving
enforcement
by aligning the
market
surveillance
regime

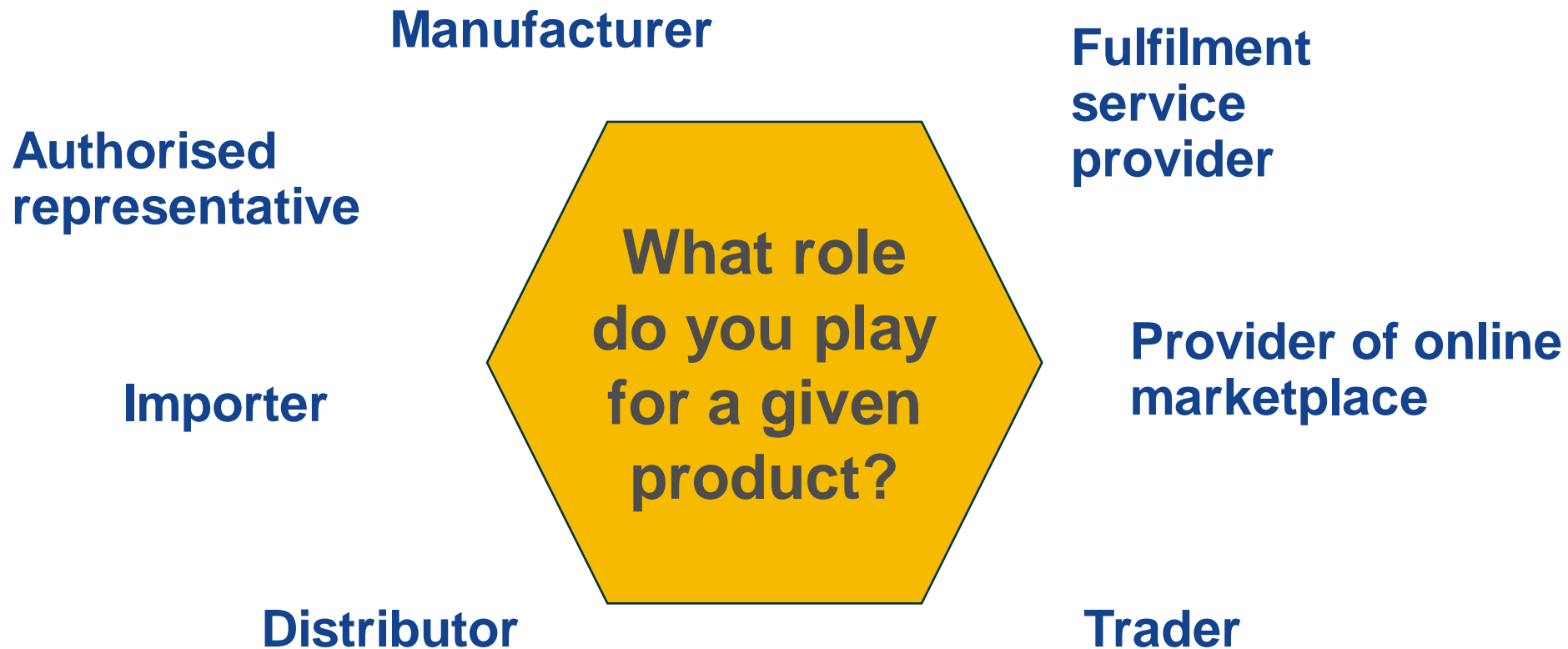
Addressing
effectiveness
of product
recalls

Modernise
general
framework



European
Commission

Who is concerned by the GPSR?



One company can have different roles !

Businesses of all sizes are concerned by the new obligations of the GPSR !

Specific guidelines assist SMEs (but no exemption from EO obligations)

GPSR subject and scope

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

Scope:



- 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
- ✓ 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



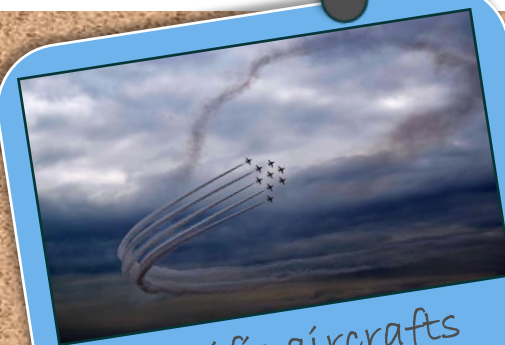
Excluded products



Food



Plant protection products



Specific aircrafts



Animal by-products



Feed & living plants and animals etc.



Antiques



Transport service

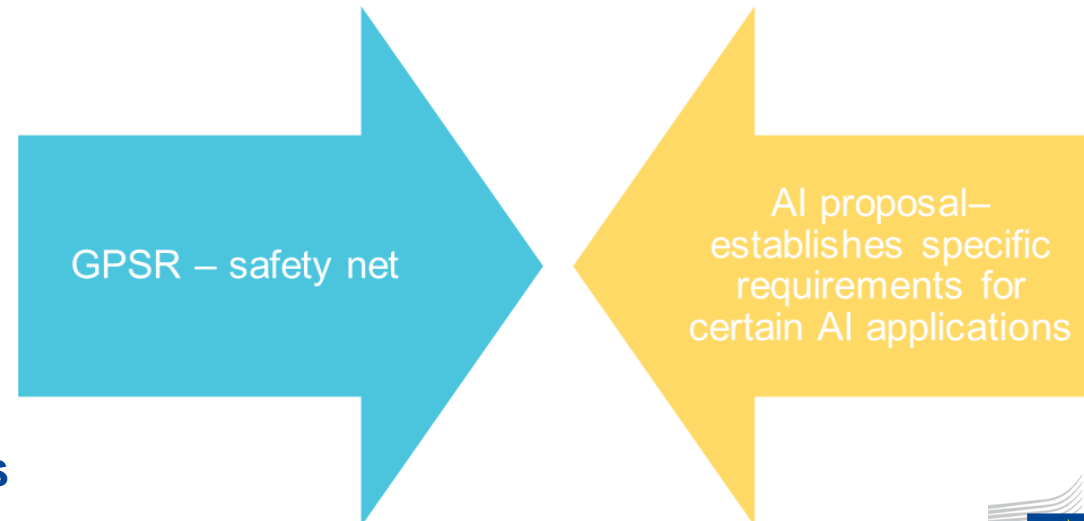


GPSR – links to other EU initiatives

- ✓ In some cases GPSR is *lex specialis*

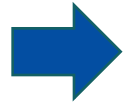


- ✓ In some cases GPSR is *lex generalis*



- ✓ It does not affect directly liability rules

GPSR - interaction with harmonised legislation



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

- Following rules are applicable to harmonised products (if there are no provisions with the same objective under the sectorial safety Union legislation):
 - ✓ 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**)
- **Chapter II** GPSR on **safety requirements** applies to harmonised products for risks not covered by EU harmonised legislation

See slides 30-36 for more details

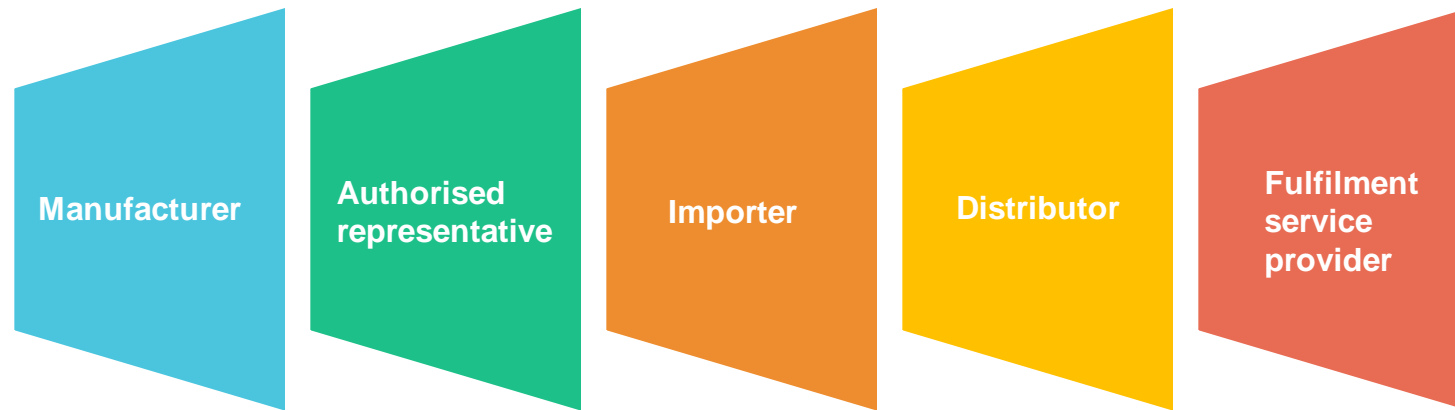
Main novelties of the GPSR

Reinforcing the safety net

- General application of **precautionary principle** by all actors when implementing the GPSR
- Addressing safety of products linked to **new technologies**:
 - 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)
- Addressing challenges posed to product safety in **online sales**:
 - **Product safety obligations of online marketplaces**:
 - Obligation to register in the Safety Gate and to follow up on orders and notices
 - Design of the interface to ensure display of traceability and safety information
 - Cooperation obligations
 - Ex post random checks
 - Close interlink and coherence with the Digital Services Act
 - **Product safety obligations for distance sales**:
 - Aligning requirements for online and offline sales: display same information online as for the products offline

Clear obligations for economic operators

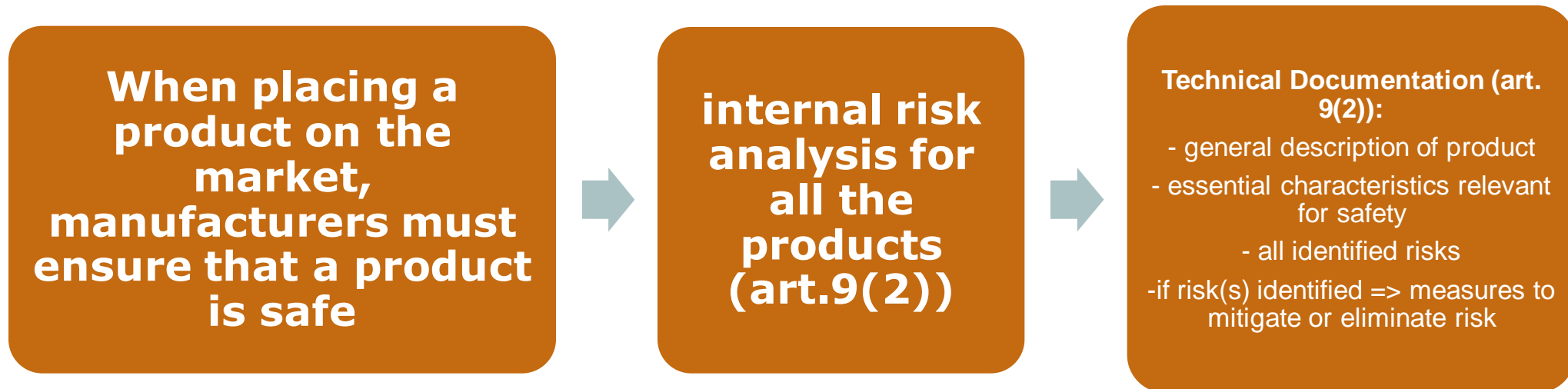
- **Introduction of specific product safety obligations for economic operators according to their respective role in the supply chain**



- **Alignment with rules applicable to harmonised products**
- **New additional tasks:**
 - accident reporting, complaint handling, substantial modification...
- **Responsible economic operator** in the EU required for **all non-harmonised products**
- Systematic use of the **Safety Business Gateway**, including for accident reporting

Manufacturer - essential role in product safety

- Manufacturer – safety by design

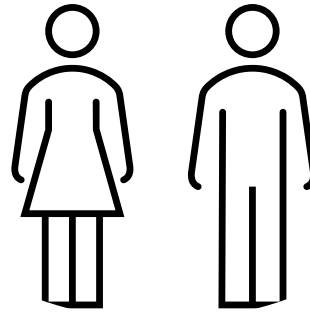


- Technical documentation is a **great tool for MSAs** to verify whether manufacturers comply with their obligation to perform an internal risk analysis and **for manufacturers** to prove they did a risk analysis
- **Importers must keep a copy** of the technical documentation for a period **of 10 years**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

Risk analysis



Characteristics



Categories of consumers



Effects on other products, cybersecurity features, evolving functionalities

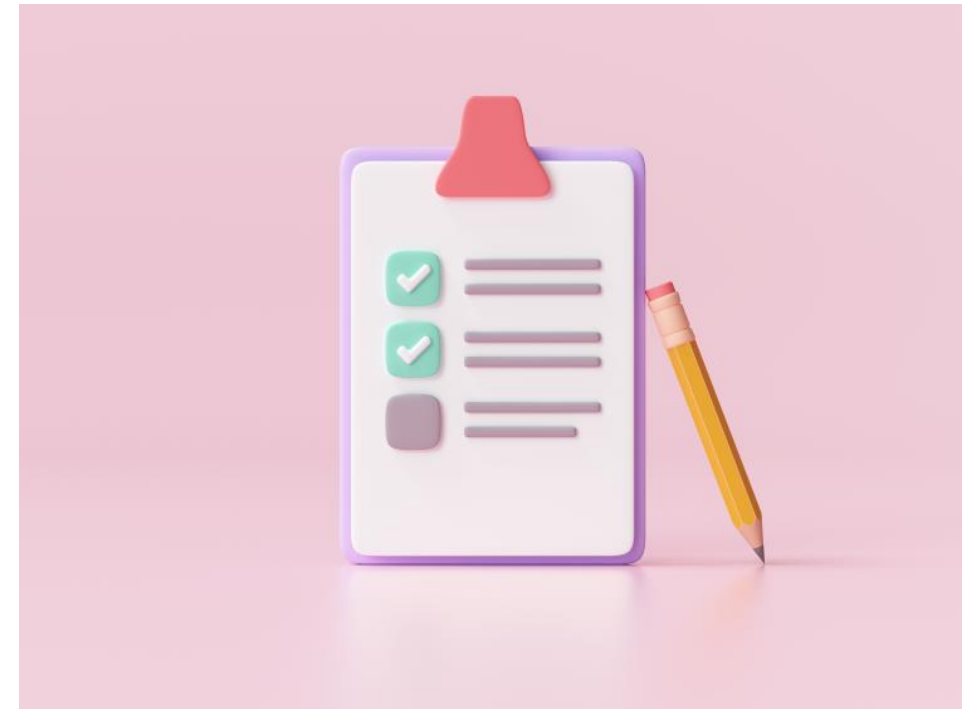
Appearance



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 referenced in the OJEU under GPSR give the “**presumption of conformity with the general safety requirement**” for the risk that they cover.
 - ⇒ 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

Who is the “**responsible person**”?

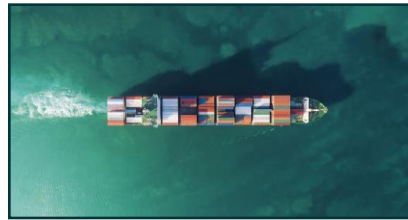
- Products covered by the GPSR coming from **outside the EU** and offered to EU consumers must have a responsible person in the EU.
- The responsible person has **additional specific tasks** related to product safety (on top of those under Reg (EU) 2019/1020):
 - ✓ Cooperation obligations
 - ✓ Regular compliance checks

Responsible person cascade

Manufacturer



Importer



Authorised representative



Fulfilment service provider



All GPSR products must have a responsible person in the EU

Do not confuse responsible person and authorised representative

Traceability requirements

WHAT

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

2. Manufacturer:

Name

Registered trade name or registered trade mark,

Postal and electronic address and, if different, the postal address or electronic address of the contact point

3. Importer:

Name

Registered trade name or registered trade mark,

Postal and electronic address and, if different, the postal address or electronic address of the contact point

4. Responsible person in the EU for this product (if not EU manufacturer or importer)

Name or registered trade mark

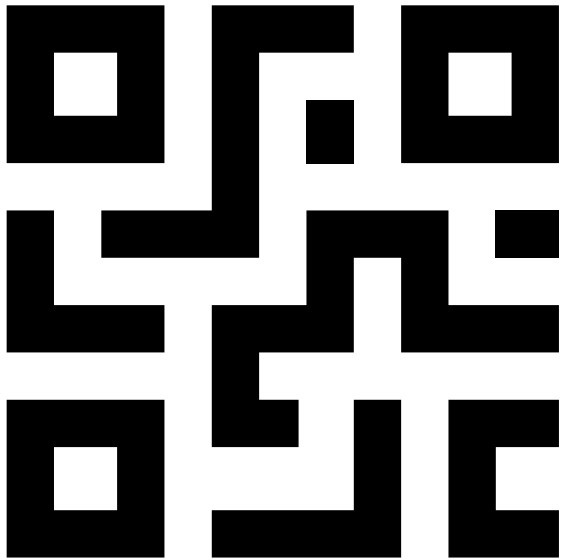
Contact details, including the postal and electronic address

WHERE

On the product if possible

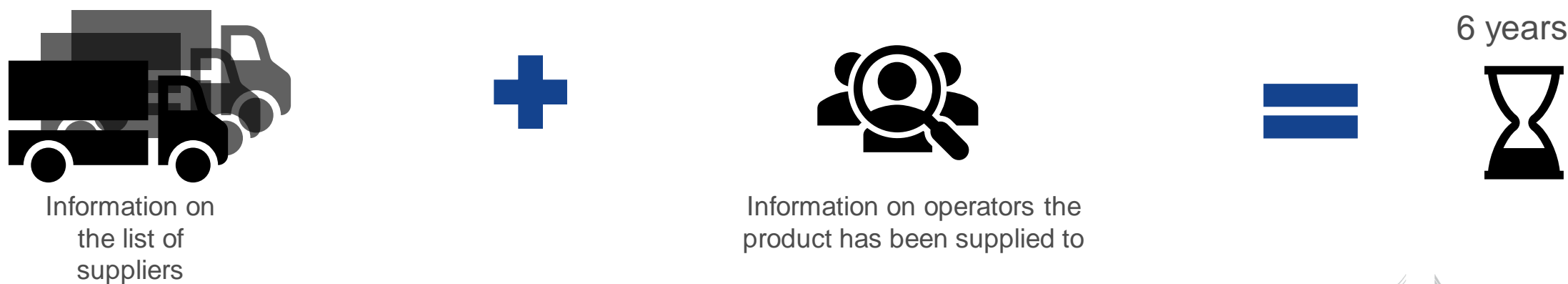
If not, on the packaging or on a doc accompanying

Labelling



Digital labelling alone is NOT sufficient!

Article 15: Cooperation and Record-keeping



Mandatory product information

PHYSICAL PRODUCT	PRODUCT OFFER in DISTANCE SALES
Type, batch or serial number or other element enabling product identification (e.g. barcode).	Information allowing the identification of the product , including a picture of it, its type and any other product identifier
Manufacturer: <ul style="list-style-type: none">- name, registered trade name or registered 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	Manufacturer: <ul style="list-style-type: none">- name, registered trade name or registered trade mark- postal and electronic address at which it can be contacted
Importer: <ul style="list-style-type: none">- 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	
Responsible person in the EU: <ul style="list-style-type: none">- name or registered trade mark- contact details, including the postal and electronic address	where the manufacturer is not established in the Union: Responsible person in the EU within the meaning of Article 16(1) of this Regulation or Article 4(1) of Regulation (EU) 2019/1020: <ul style="list-style-type: none">- name- postal and electronic address
clear instructions and safety information in a language which can be easily understood by consumers	any warning or safety information to be affixed to the product or to the packaging or included in an accompanying document in accordance with the GPSR or the applicable Union harmonisation legislation in a language which can be easily understood by consumers

Making product recalls more effective

- **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

Product Safety Recall

[COMPANY NAME] RECALLS [NAME OF THE PRODUCT]

[Insert PICTURE OF PRODUCT & graphical indication of where to find identification numbers (if applicable)]

Include PRODUCT IDENTIFICATION INFORMATION:

- Identification numbers, such as batch and serial number
- Information on where and when product was sold (if available)

HAZARD

- Clearly state the hazard the product poses and why
- Don't use any terms or expressions that may decrease consumers' perception of risk, e.g. "voluntary"/"precautionary", "in rare/specific situations"

WHAT TO DO

- Instruct consumers to stop using the product immediately
- Clearly explain how to participate in the recall (e.g., return to point of sale, schedule appointment for in-house pick-up/repair, etc.)

REMEDY

- Clearly describe the remedy available to consumers (e.g., repair, replacement, refund)

CONTACT

- Provide website and free phone number, interactive online service and/or email address where consumers can get more information

[APOLOGY (OPTIONAL)]

SPREAD THE NEWS: Tell your friends and family about this recall!

European Commission

Recall notice template

Product Safety Recall		Date
[Company name] recalls [product]		
<p><i>Insert picture(s) of product and, if applicable, a graphical indication of where to find product identification numbers on the product.</i></p> <p><i>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.</i></p>		
<p>Include a clear description of the recalled product, including product identification information:</p> <ul style="list-style-type: none">• 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?		
<ul style="list-style-type: none">• 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		
<ul style="list-style-type: none">• 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		
<ul style="list-style-type: none">• 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.		

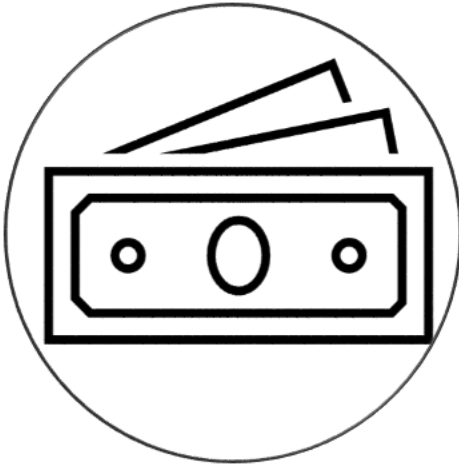
Spread the word about this recall, especially if you know that the recalled product was offered, lent or sold to someone else

Product Safety Recall		Date
Contact		
<ul style="list-style-type: none">• 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).		
[Apology (optional)]		
<p>[Links to social media post /website informing about the recall (optional)]</p> <p>[QR code or other technical solution leading to recall page/more information (optional)]</p>		

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:



Adequate
Refund



Repair



Replacement

Other novelties of the GPSR

- Integrating **food-imitating products** safety assessment
 - Repeal the **Food-imitating product Directive** and introduce aspects related to food imitating products in the safety assessment under GPSR
 - Extension of the **child-appealing** aspects to the safety assessment
- **International cooperation**
 - Different types of information exchange → different instruments
- Change of the **legal instrument** into Regulation
 - Ensure even application via Regulation



What's new in the GPSR for harmonised products?

GPSR - interaction with harmonised legislation

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

- Following rules are applicable to harmonised products (if there are no provisions with the same objective under the sectorial safety Union legislation):
 - ✓ 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

Novelties for harmonised products

- **Chapter II GPSR on safety requirements** applies to harmonised products **for risks not covered by EU harmonised legislation**
 - New non-exhaustive **list of aspects for assessing the safety of products** (including aspects for new technology products, child-appealing, food imitating, etc)
- **Chapter III, Section 2 : obligations of economic operators**
 - **Obligations of economic operators on accident reporting (Art 20)**
 - Mandatory reporting of known accidents by economic operators
 - Manufacturer must notify MSAs via Safety Business Gateway
 - **Obligations of economic operators on distance sales (Art 19)**
 - Same product information online as it is with the product offline : useful for traceability and market surveillance

Mandatory product information



New for harmonised products

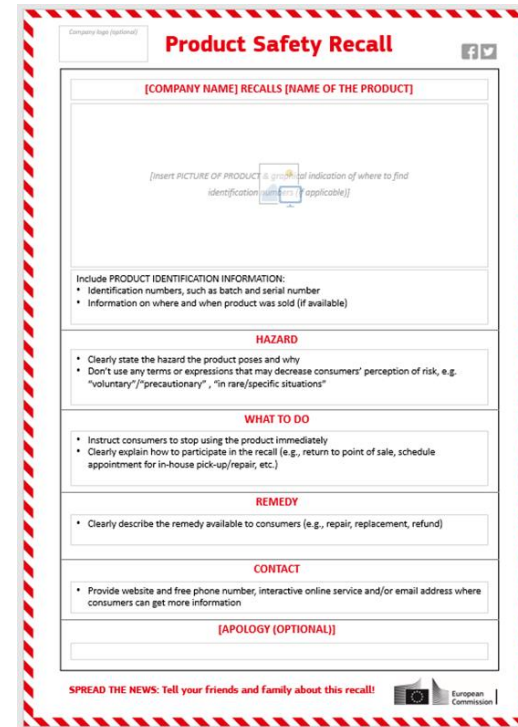
PHYSICAL PRODUCT	PRODUCT OFFER in DISTANCE SALES
Type, batch or serial number or other element enabling product identification (e.g. barcode).	Information allowing the identification of the product , including a picture of it, its type and any other product identifier
Manufacturer: <ul style="list-style-type: none">- name, registered trade name or registered 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	Manufacturer: <ul style="list-style-type: none">- name, registered trade name or registered trade mark- postal and electronic address at which it can be contacted
Importer: <ul style="list-style-type: none">- 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	
Responsible person in the EU: <ul style="list-style-type: none">- name or registered trade mark- contact details, including the postal and electronic address	where the manufacturer is not established in the Union: Responsible person in the EU within the meaning of Article 16(1) of this Regulation or Article 4(1) of Regulation (EU) 2019/1020: <ul style="list-style-type: none">- name- postal and electronic address
clear instructions and safety information in a language which can be easily understood by consumers	any warning or safety information to be affixed to the product or to the packaging or included in an accompanying document in accordance with the GPSR or the applicable Union harmonisation legislation in a language which can be easily understood by consumers

Novelties for harmonised products

- **Chapter IV on product safety obligations of providers of online marketplaces:**
 - Obligation to register in the Safety Gate and to follow up on orders and notices
 - Design of the interface to ensure display of traceability and safety information
 - Cooperation obligations
 - Ex post random checks
 - Close interlink and coherence with the Digital Services Act
- **Chapter VI on Safety Gate Rapid Alert System and Safety Business Gateway:**
 - **Safety Gate Rapid Alert System (Art 25 + 26)**
 - Notification obligations in Safety Gate for MS on serious risk cases within 4 working days after the corrective action is taken
 - 4 days working days deadline for the Commission's check
 - Obligation to inform COM about all other corrective measures as well (choice of info tool)
 - **Safety Business Gateway (Art 27)**
 - Commission's obligation to maintain a web portal enabling the businesses to provide the required information to the MSAs in an easy way

Novelties for harmonised products

- **Chapter VIII on Right to information and to a remedy**
 - **Right to information**
 - **MS:** obligation to provide consumers and interested parties the opportunity to submit complaints (Art 33)
 - **COM:** obligation to maintain Safety Gate Portal with possibility for consumers and interested parties to inform about possible dangerous products, to develop an interoperable interface for providers of online marketplaces (Art 34)
 - **Businesses:** obligation to inform consumers about product safety recalls and safety warnings (Art 35)
 - **Product recalls**
 - Mandatory elements for the recall notice
 - Template for the recall notice provided by implementing act
 - **Mandatory remedies** in case of product recall:
at least 2 between: repair, replacement or adequate refund
 - **Memoranda of understanding**
 - **Representative actions**



The image shows a template for a Product Safety Recall notice, enclosed in a red and white striped border. The form is titled "Product Safety Recall" and includes a "Company logo (optional)" field. The main heading is "[COMPANY NAME] RECALLS [NAME OF THE PRODUCT]". Below this is a placeholder for a product picture with a note: "[Insert PICTURE OF PRODUCT & graphical indication of where to find identification numbers (if applicable)]". The form is divided into several sections: "Include PRODUCT IDENTIFICATION INFORMATION:" with bullet points for identification numbers and information on where and when the product was sold; "HAZARD" with instructions to state the hazard and avoid certain terms; "WHAT TO DO" with instructions to stop using the product and explain how to participate in the recall; "REMEDY" with instructions to describe the available remedy; "CONTACT" with instructions to provide contact information; and an optional "[APOLOGY (OPTIONAL)]" section. At the bottom, there is a red banner that says "SPREAD THE NEWS: Tell your friends and family about this recall!" and the European Commission logo.

Important to know

Important to know for businesses



EU products rules apply to **all products** on the EU market: products manufactured outside the EU and targeting EU consumers **should also comply with EU rules**

→ Products must be safe

→ All specific product obligations (risk assessment, technical documentation, traceability information, instructions, warnings, recalls provisions, complaint handling, etc)



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** and **ensure corrective actions are taken**

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



Product safety = consumer trust + better health