



RecallDesk
Taking Safety Seriously

The New EU General Product Safety Regulation

Presentation given for NAMM
29 May 2024

By Rutger Oldenhuis LL.M. | @RecallDesk

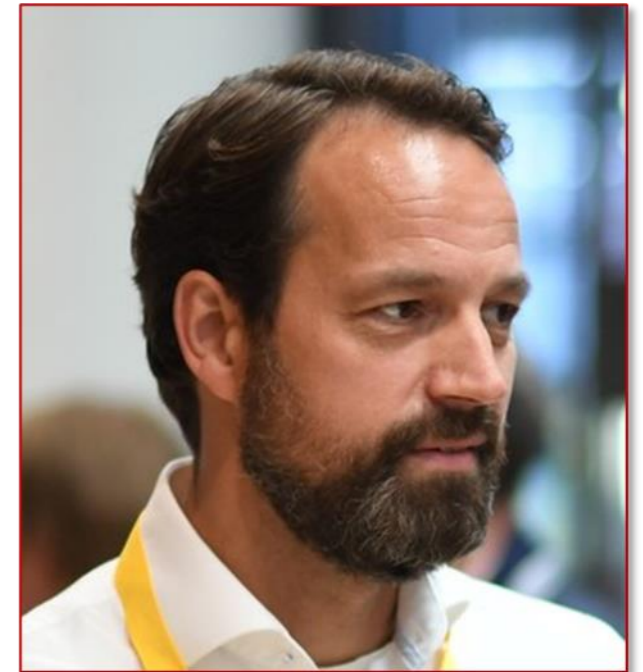
Introduction

Rutger Oldenhuis LLM

Family man, music man, sportsman

Legal Consultant | Regulation & Compliance | Product Safety & Recall

- 20+ years of legal experience
- Former Head of Legal at Shimano Europe
- Founder of RecallDesk since 2021
- specializing in product compliance, safety, and recalls
- writer/contributor for BikeEurope Magazine, Sporting Goods Intelligence Europe, Eyewear Intelligence
- Member of several NEN standard committees
- For case studies: www.recalldesk.com



About RecallDesk

One-stop shop for product compliance, product safety and recalls

Services include:

Compliance/prevention:

- QuickScan
- CAPA plan
- Risk assessment (pre-market)
- Product compliance
- Product manuals
- Product labeling
- Legal advice
- Supply chain contracts
- Insurance advice
- Training & webinars
- *Authorised representative services*

(Potential) crisis:

- Recall management/support
- Risk assessment (post-market)
- Corrective action strategy
- Communication
- Authorities
- Legal advice
- Insurance & Claims
- Expert Witness



Partnerships & Contributions



Office for Product
Safety & Standards



BIKE europe

EDIII
Publications

SGI Europe
Sporting Goods Intelligence

Outdoor
INDUSTRY COMPASS

Eyewear
INTELLIGENCE

SHOE
INTELLIGENCE



The EU Legal Framework for Product Safety



Simplified for the purpose of this presentation



Outline

- EU General Product Safety Directive (2001/95/EC) will be **replaced** by the EU General Product Safety Regulation (2023/988).
- The General Product Safety Regulation ("GPSR") will enter into force on **13 December 2024**.
- The GPSR will be a **game changer** for companies selling consumer goods in the EU.
- This presentation highlights the main **changes** and critical points of the GPSR compared to the GPSD.



Form, Scope and Position

- **Form.** EU Regulation vs. EU Directive.
- **Scope.**
 - More detailed and specific provisions than the GPSD
 - Will also cover food imitation products (repealing Directive 87/357/EEC)
- **Position.** Safety net+



The GPSR Is Going Mental

- Under the GPSR, the term 'product safety' takes on a much broader meaning and includes 'health'
- The GPSR refers to the WHO's definition of 'health'
- The World Health Organization defines 'health' as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.



Risk Assessment (pre-market) and Technical Documentation

The GPSR mandates:

Before placing their products on the market, manufacturers shall carry out an **internal risk analysis** and draw up **technical documentation** containing at least a general description of the product and its essential characteristics relevant for assessing its safety.

Where appropriate with regard to possible risks related to the product, the technical documentation referred to in the first subparagraph shall also contain, as applicable:

- a) an analysis of the possible risks related to the product and the solutions adopted to eliminate or mitigate such risks, including the outcome of any reports related to tests conducted by the manufacturer or by another party on their behalf; and
- b) the list of any relevant European standards.

→ Keep up to date and for 10 years.



QR Code Not Accepted as Single Means

“Economic operators may **additionally** make the information [...] available in a digital format by means of **electronic technical solutions** clearly visible on the product or, where that is not possible, on its packaging or in a document accompanying the product.”



Online platforms as the 'new market surveillance authorities'

- **Providers of online platforms** must ensure - through a battery of due diligence obligations - that traders using their platform only sell products that comply with applicable laws and regulations.
- If traders want to sell their products via Amazon or the like, they should be **in control** of their product compliance and safety processes.
- In case of repeated non-compliance, pursuant to the GPSR, providers of online platform will have to **suspend** their services to this trader until further notice.

→ This makes providers of online platforms de facto a new/extra 'gatekeeper' when it comes to product compliance and safety.



Traders Outside the EU Selling Directly To The EU Should Have A Responsible Person in the EU (1)

“A product covered by this Regulation shall not be placed on the market unless there is an economic operator established in the Union [...]”

- **Companies established outside the EU** can no longer sell directly to consumers in the EU through online channels without having a representative established in the EU.
- The representative established in the EU will be the person or company to be addressed if products do not comply with EU legislation.



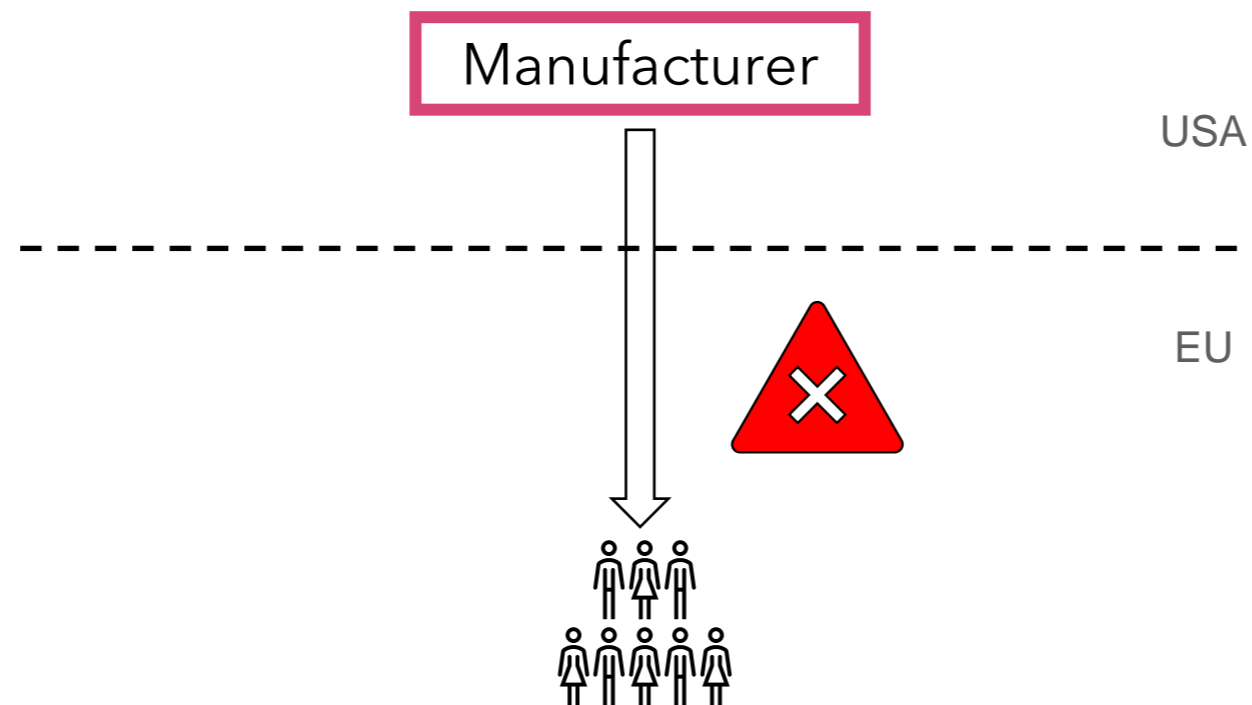
Traders Outside the EU Selling Directly To The EU Should Have A Responsible Person in the EU (2)

'economic operator' means 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 this Regulation

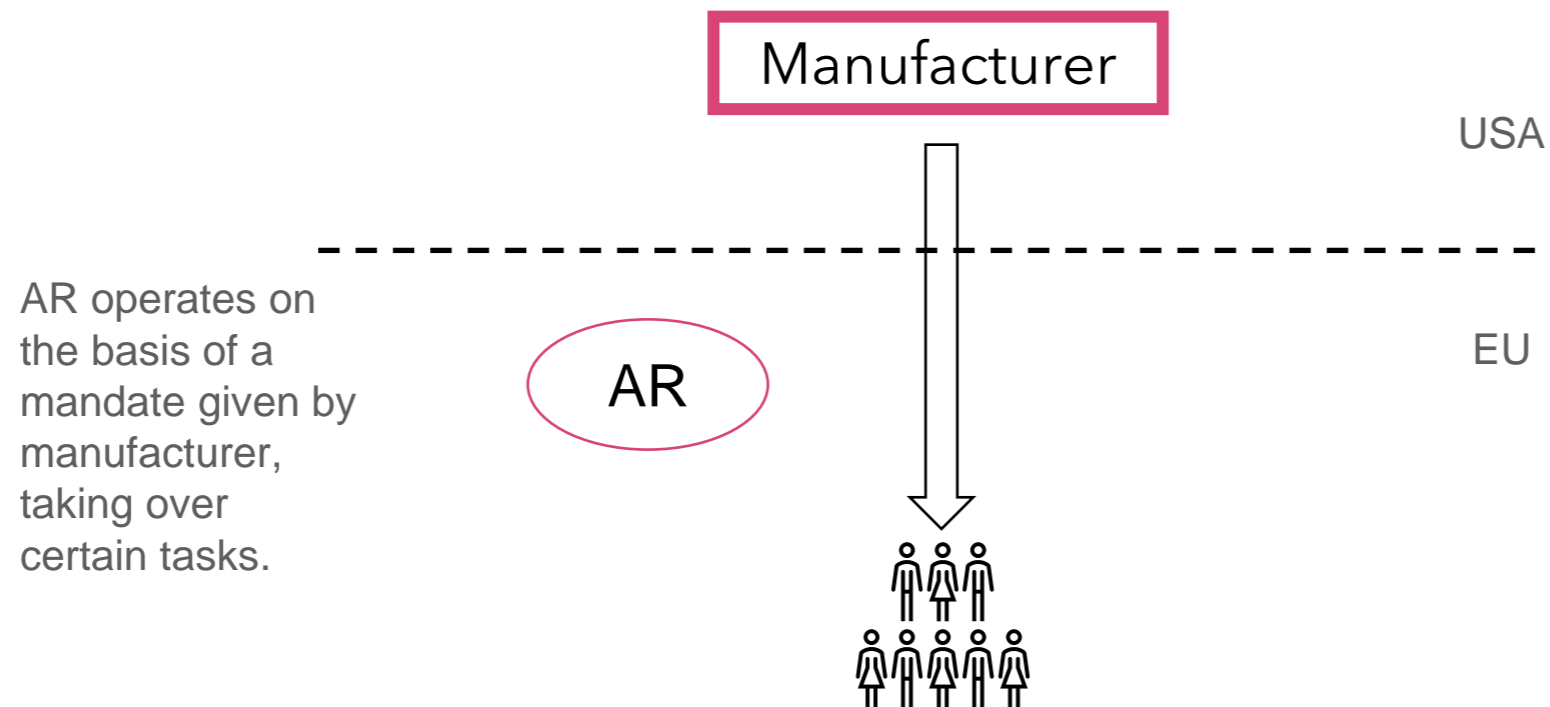
FSP: at least two of following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved, excluding postal services



Traders Outside the EU Selling Directly To The EU Should Have A Responsible Person in the EU (3)



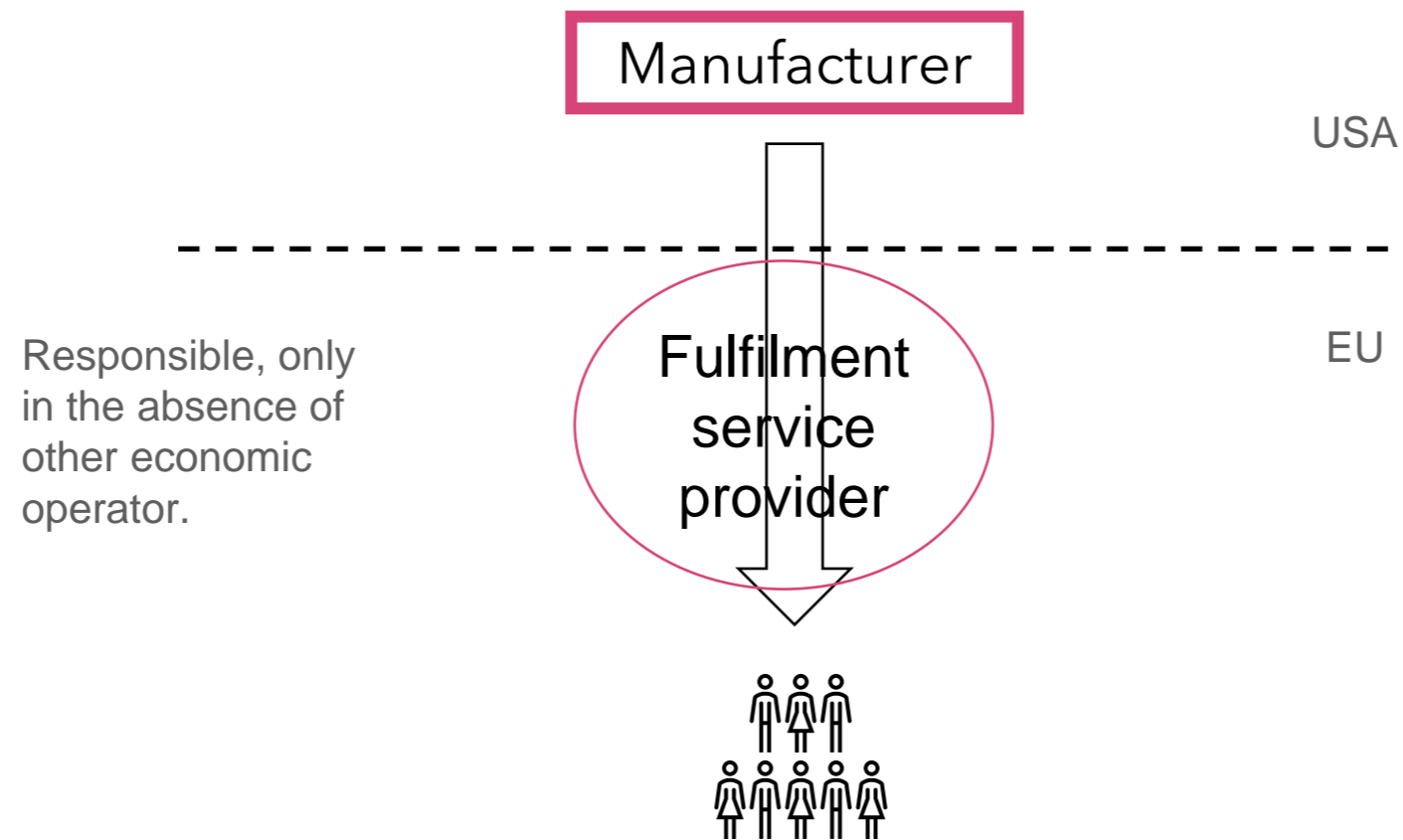
Traders Outside the EU Selling Directly To The EU Should Have A Responsible Person in the EU (4)



NB: Details of manufacturer and AR on product, or on/in packaging



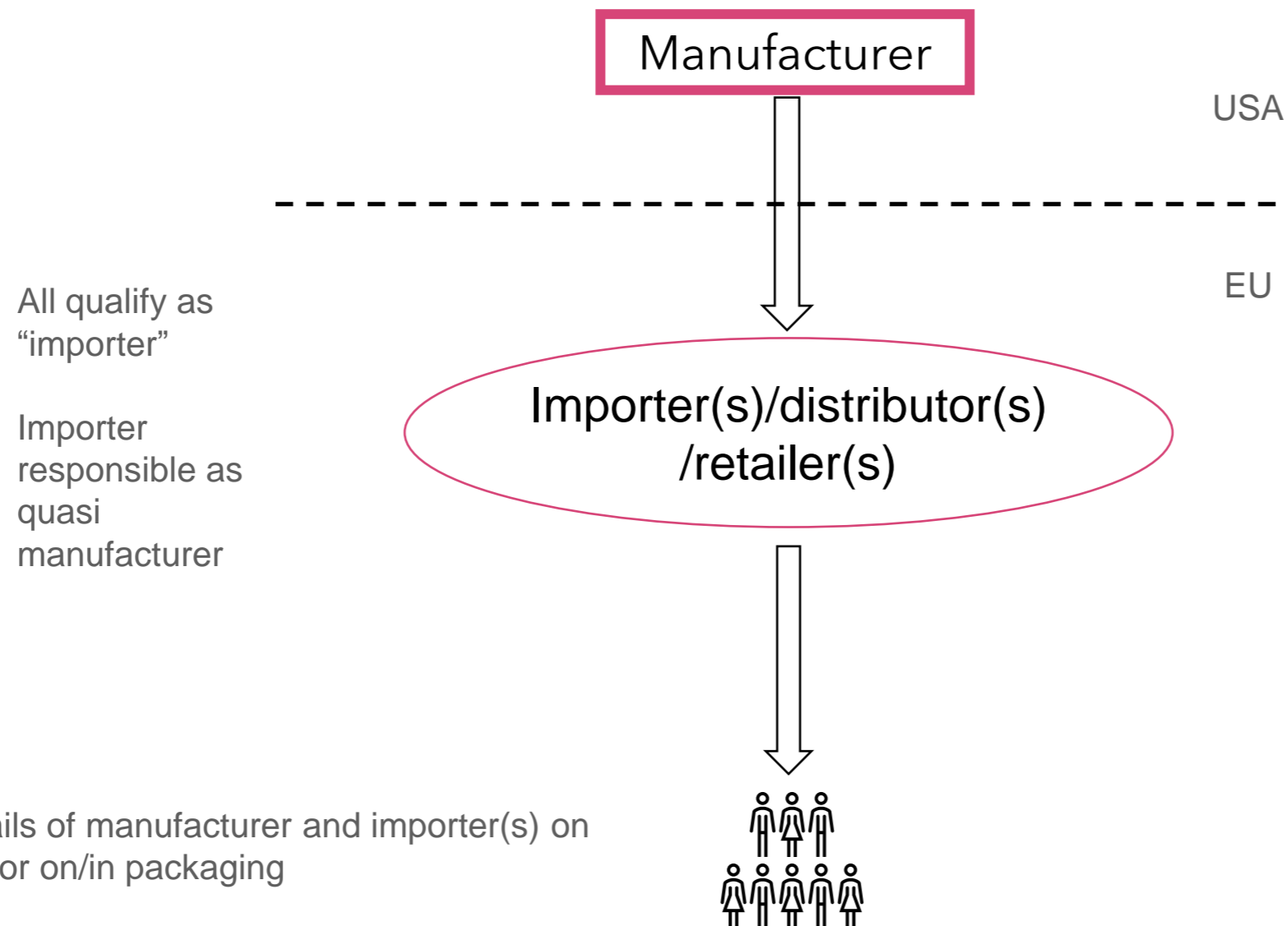
Traders Outside the EU Selling Directly To The EU Should Have a Responsible Person in the EU (5)



NB: Details of manufacturer and FSP on product, or on/in packaging



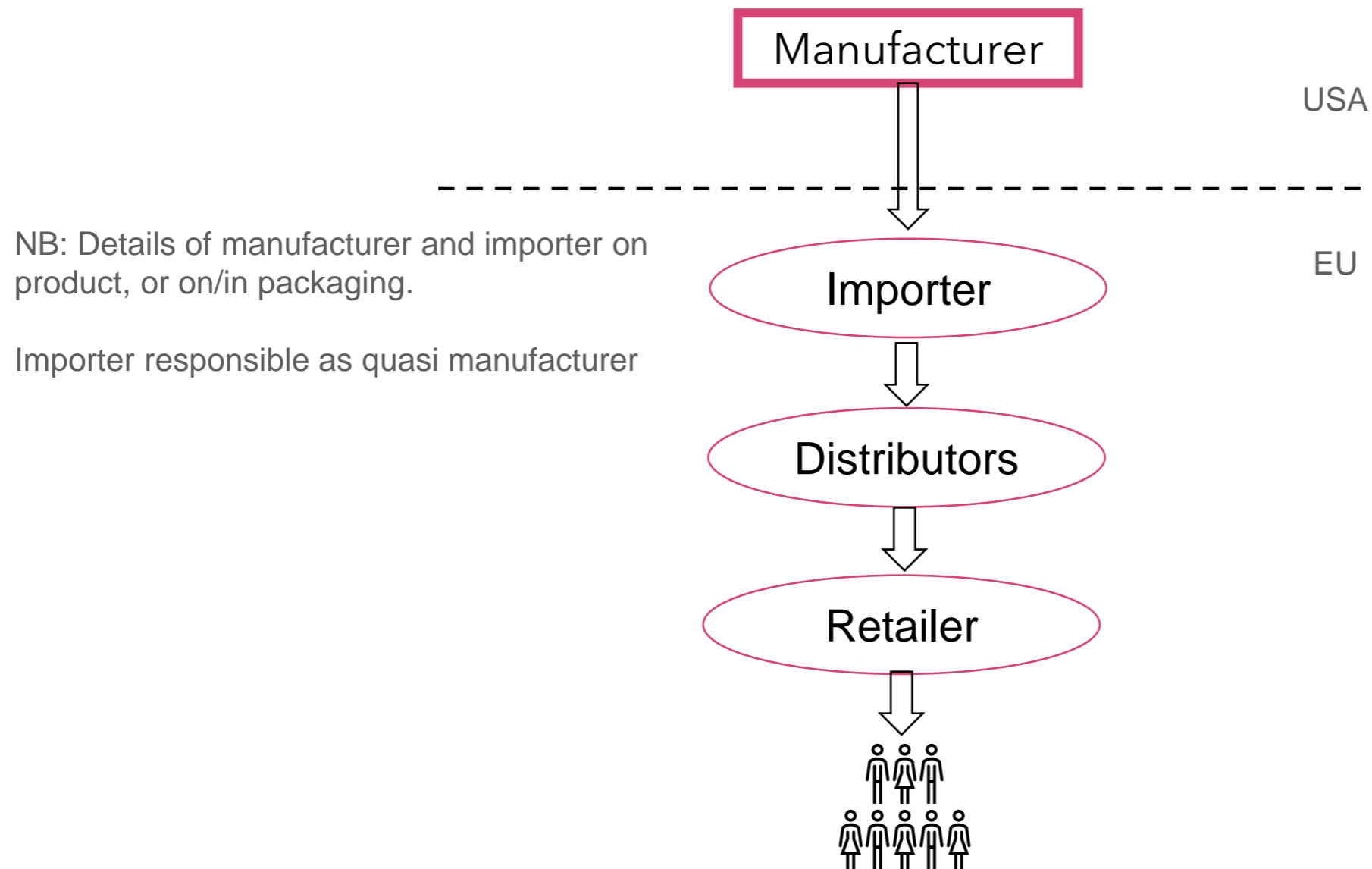
Traders Outside the EU Selling Directly To The EU Should Have A Responsible Person in the EU (6)



NB: Details of manufacturer and importer(s) on product, or on/in packaging



Traders Outside the EU Selling Directly To The EU Should Have A Responsible Person in the EU (?)



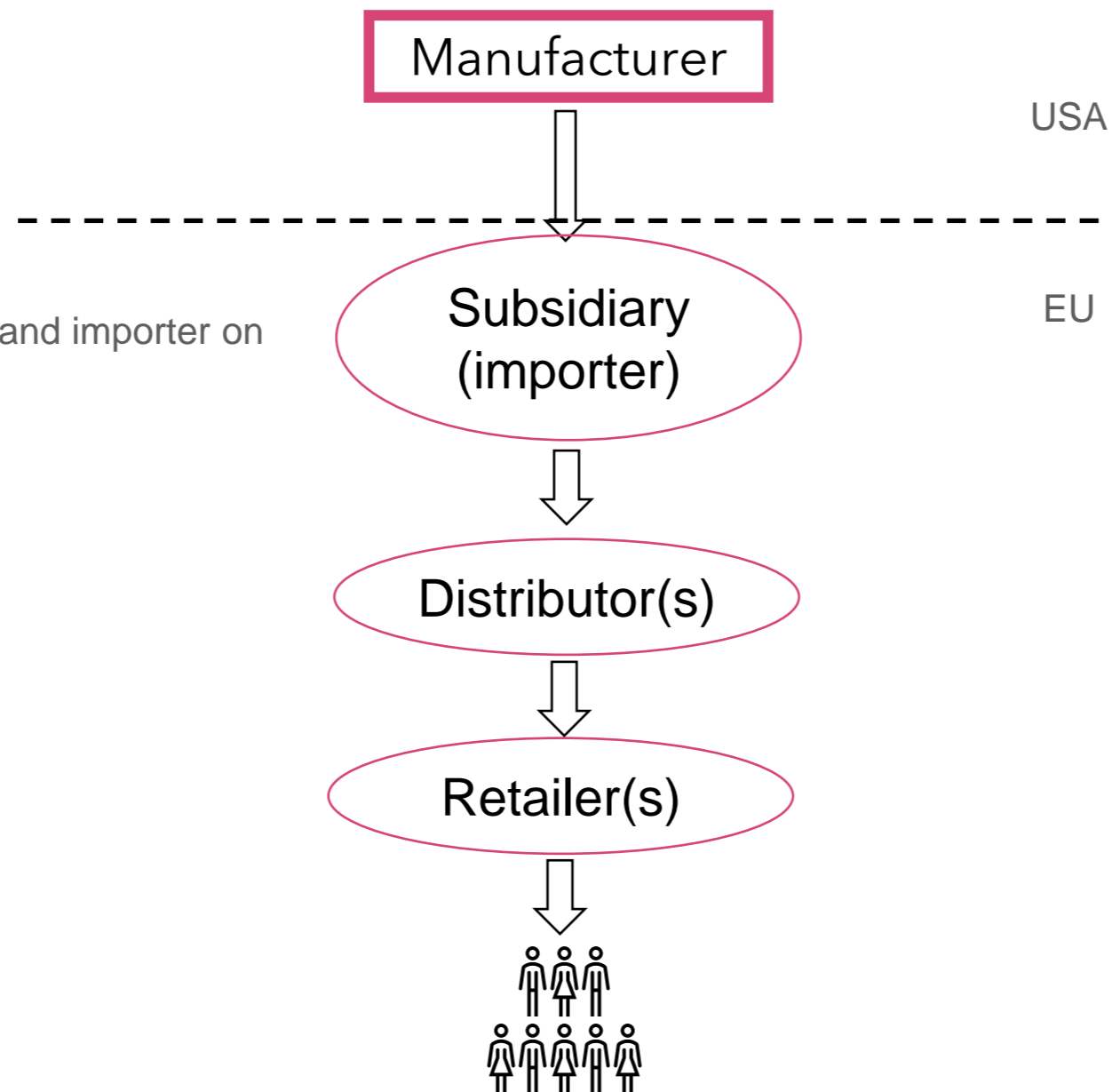
Traders Outside the EU Selling Directly To The EU Should Have A Responsible Person in the EU (8)

Complicating factors:

- Additional labeling by importers
- Sharing sensitive information with customers/competitors
- Proposal EU Product Liability Directive



Traders Outside the EU Selling Directly To The EU Should Have A Responsible Person in the EU (9)



NB: Details of manufacturer and importer on product, or on/in packaging



Obligations In Case Of Online Sales

The offer of products shall indicate among others:

- [...]
- where the manufacturer is **not established in the EU**, the name, postal and electronic address of the **responsible person in the EU**;
- any **warning or safety information**.



New: Accident Reporting Duty

- Obligation for manufacturers to report **“without undue delay”** accidents caused by products they have placed on the market.
- The text of the GPSR is somewhat vague but seems to suggest that the reporting obligation pertains only to incidents resulting in **death or serious adverse effects** on health and safety, whether permanent or temporary, including injuries, bodily harm, illnesses, and chronic health effects. The expected **guidance** from the Commission may clarify whether indeed this is the correct interpretation.
- The report must be made to the **competent Market Surveillance Authority** of the Member State where the accident occurred.
- Other economic operators and **providers of online platforms** also play an important role.



Internal Product Safety Process

- GPSR: internal product safety processes **compulsory**.
- To be determined by economic operator in relation to their role in supply chain and type of products.
- How: e.g. organisational procedures, guidelines, standards.

Examples:

ISO 10377 + ISO 10393



Recall? At Least Two Remedies

In the event of a recall, the GPSR stipulates that consumers should be given a choice of **at least two** of the following remedies:

- repair, replacement or a refund.

Only **one remedy** if the other remedies are **impossible** or **disproportionate**.



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Beware Of The Snag!

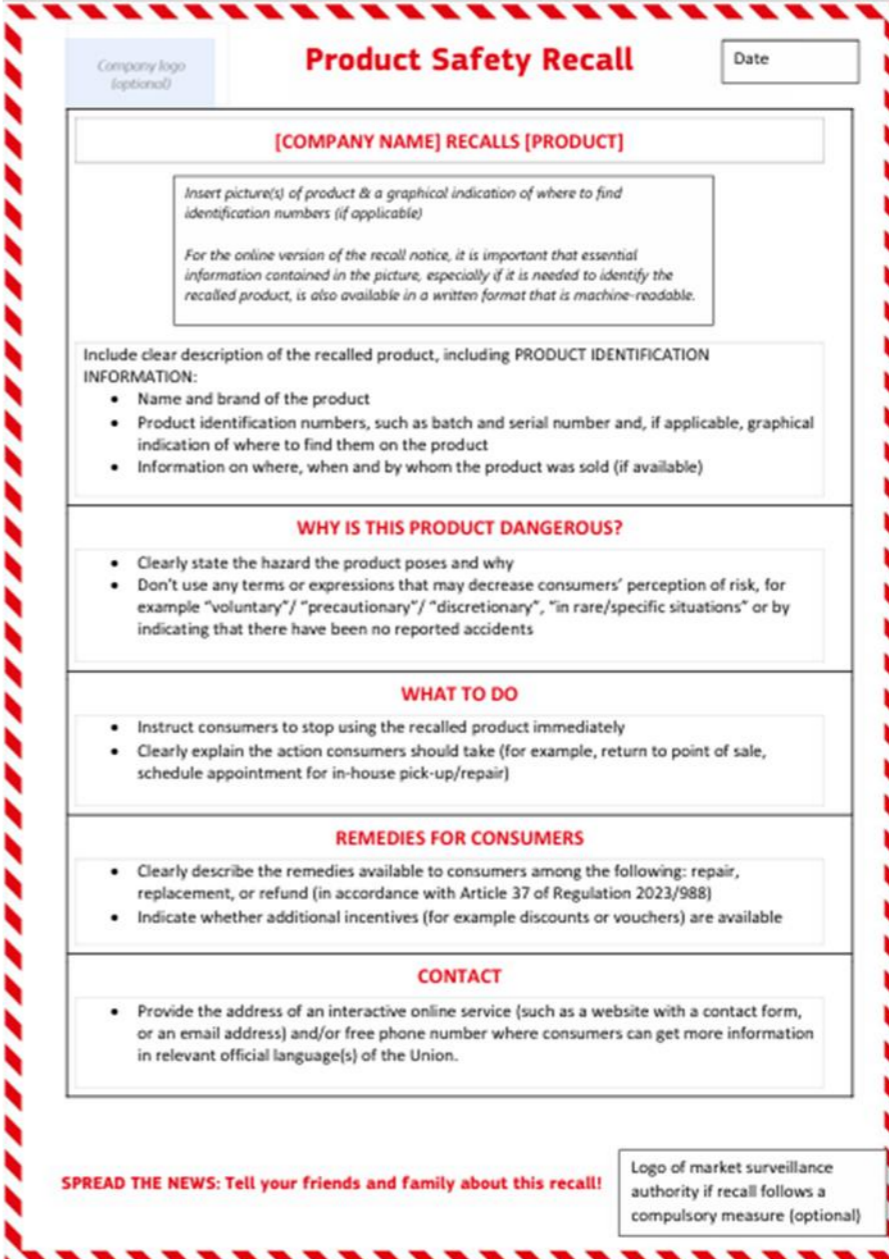
- In the event of a recall, the consumer must be instructed to immediately **stop using** the affected product.
- In addition, in the event of a recall, the economic operator must **collect** the unsafe product from the consumer if it is not portable.

How about a **car**?



Recall notice template

- EU Commission has just published a recall notice template that must be used.



Product Safety Recall

Company logo (optional) Date

[COMPANY NAME] RECALLS [PRODUCT]

Insert picture(s) of product & a graphical indication of where to find identification numbers (if applicable)

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 written format that is machine-readable.

Include 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, 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
- Don't use any terms or expressions that may decrease consumers' perception of risk, for example "voluntary" / "precautionary" / "discretionary", "in rare/specific situations" or by indicating that there have been no reported accidents

WHAT TO DO

- Instruct consumers to stop using the recalled product immediately
- Clearly explain the action consumers should take (for example, return to point of sale, schedule appointment for in-house pick-up/repair)

REMEDIES FOR CONSUMERS

- Clearly describe the remedies available to consumers among the following: repair, replacement, or refund (in accordance with Article 37 of Regulation 2023/988)
- Indicate whether additional incentives (for example discounts or vouchers) are available

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.

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

Logo of market surveillance authority if recall follows a compulsory measure (optional)



Consumer Complaints

- It will be **easier** for consumers to submit **complaints** to authorities.
- Manufacturers and their **reputation** for product quality and safety will therefore be **more exposed**.



Penalties

- GPSR introduces **penalties** for those who violate the GPSR.
- Expected they will play a significant deterrent effect for economic operators.



Key Take-outs

- GPSR will be relevant for all consumer products, even if covered by sectoral legislation.
- GPSR will be a **game changer** for companies selling consumer products in the EU.

Be prepared!



Questions?

Thank you!

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