

 TaylorWessing

Looking ahead for your consumer products

The proposed changes to the European product safety regime

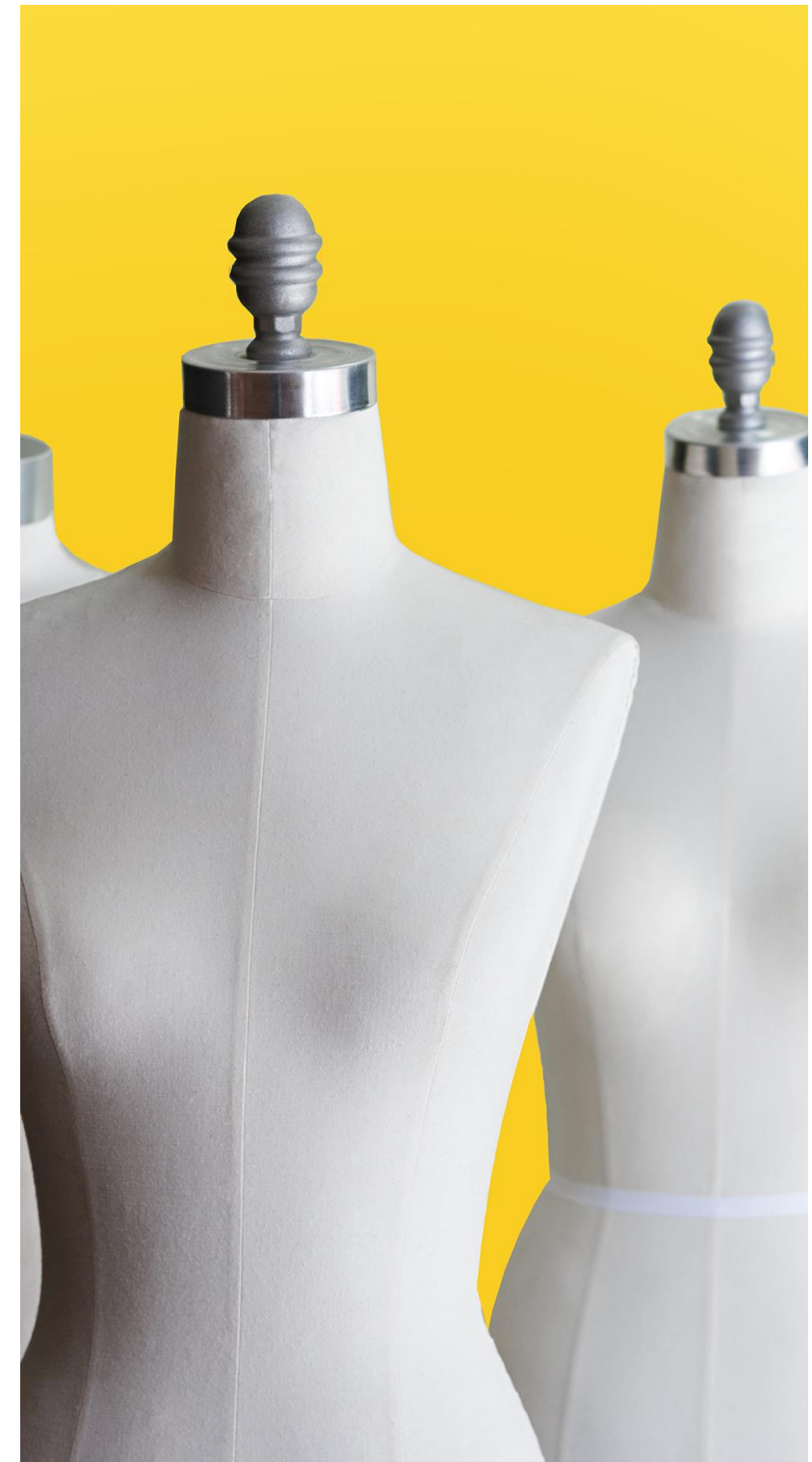
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Private and confidential

An overview of the session

1. The current product safety regime for consumer products - an overview of the General Product Safety Directive ("GPSD")
2. What is newly proposed The General Product Safety Regulation ("GPSR")?
3. What are the key changes being proposed pursuant to the GPSR?
4. How will the GPSR affect the UK?
5. What should you do next?



The current product safety regime for consumer products (The GPSD)

- The General Product Safety Directive 2001/95/EC ("**GPSD**") aims to ensure the safety of consumer products. It applies to those products which are not regulated by sector specific rules e.g., toys, electricals, and medical devices. For these products, the GPSD only applies to the extent that an issue is not covered by sector specific legislation.
- The GPSD does not expressly include or exclude "software" as a product but application to connected products unclear.
- The GPSD requires that producers only place "safe products" on the market. In accordance with Article 2(b) of the GPSD, a safe product is:

Any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular:

- (i) the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;*
- (ii) the effect on other products, where it is reasonably foreseeable that it will be used with other products;*
- (iii) the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;*
- (iv) the categories of consumers at risk when using the product, in particular children and the elderly.*

The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to be "dangerous".

- The conformity of a product to national standards is also relevant to the assessment of whether a product is safe.

The GPSD

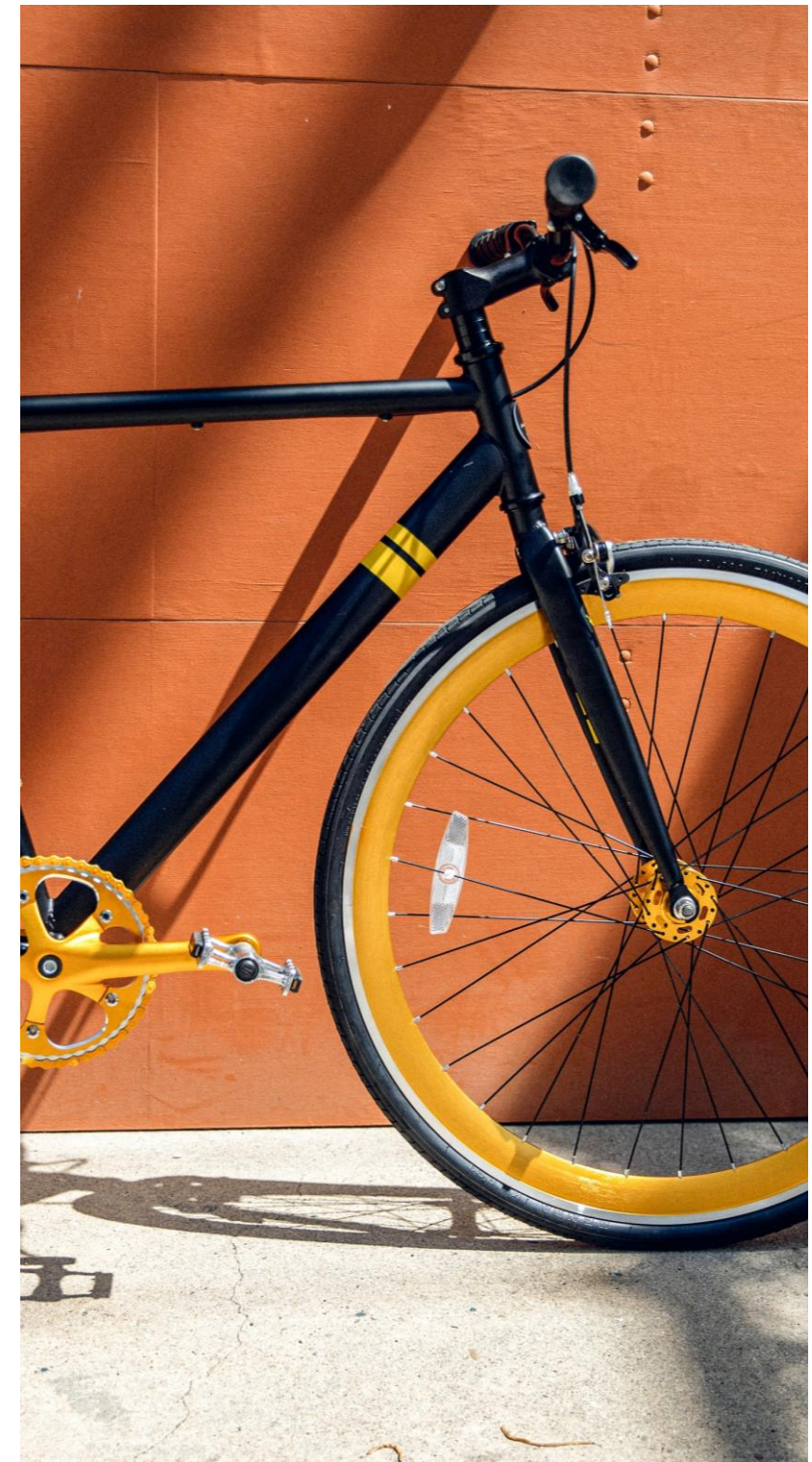
- Under the GPSD, producers are required to provide consumers with enough information for them to assess the risk which a product might pose. The producer is the manufacturer, or their representative in the EU, or the importer, or another party in the supply chain insofar as their activities may affect the safety properties of the product.
- Distributors (any party in the supply chain whose activity does not affect the safety properties of the product) are required to act with due care to help ensure compliance with the applicable safety requirements, in particular by not supplying products which they know or should have presumed, on the basis of the information in their possession and as professionals, do not comply with those requirements. They are also required to participate in monitoring the safety of products placed on the market.
- Both producers and distributors are required to cooperate with competent authorities on issues related to product safety.
- Online marketplaces currently not defined.
- The GPSD applies to all member states of the EU and is retained EU law in the UK post-Brexit.

What is The General Product Safety Regulation ("GPSR")?

- Nov 2022, the European Council and the European Parliament reached a provisional agreement on The General Product Safety Regulation ("**GPSR**"), which will replace the GPSD.
- Similar to the GPSD, the GPSR will also require that economic operators only place / make available on the EU market safe products.
- The GPSR will apply to all products defined in Article 3(1) as being " ... **any item, interconnected or not 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.**"
- As such, the GPSR is intended to address the safety challenges presented by emerging technologies, including the use of AI and connected devices – (1) software incorporated into a product before placed on the market (2) third-party software downloaded onto the product (3) software updates
- This includes new, second-hand, refurbished, reused, and recycled products (unless the product is clearly marked as being sold for repair or reconditioning prior to being used or antiques).
- But it will not apply to products that are regulated by separate EU legislation, such as medical devices, medicines, and food (except in respect of aspects not covered by that legislation).

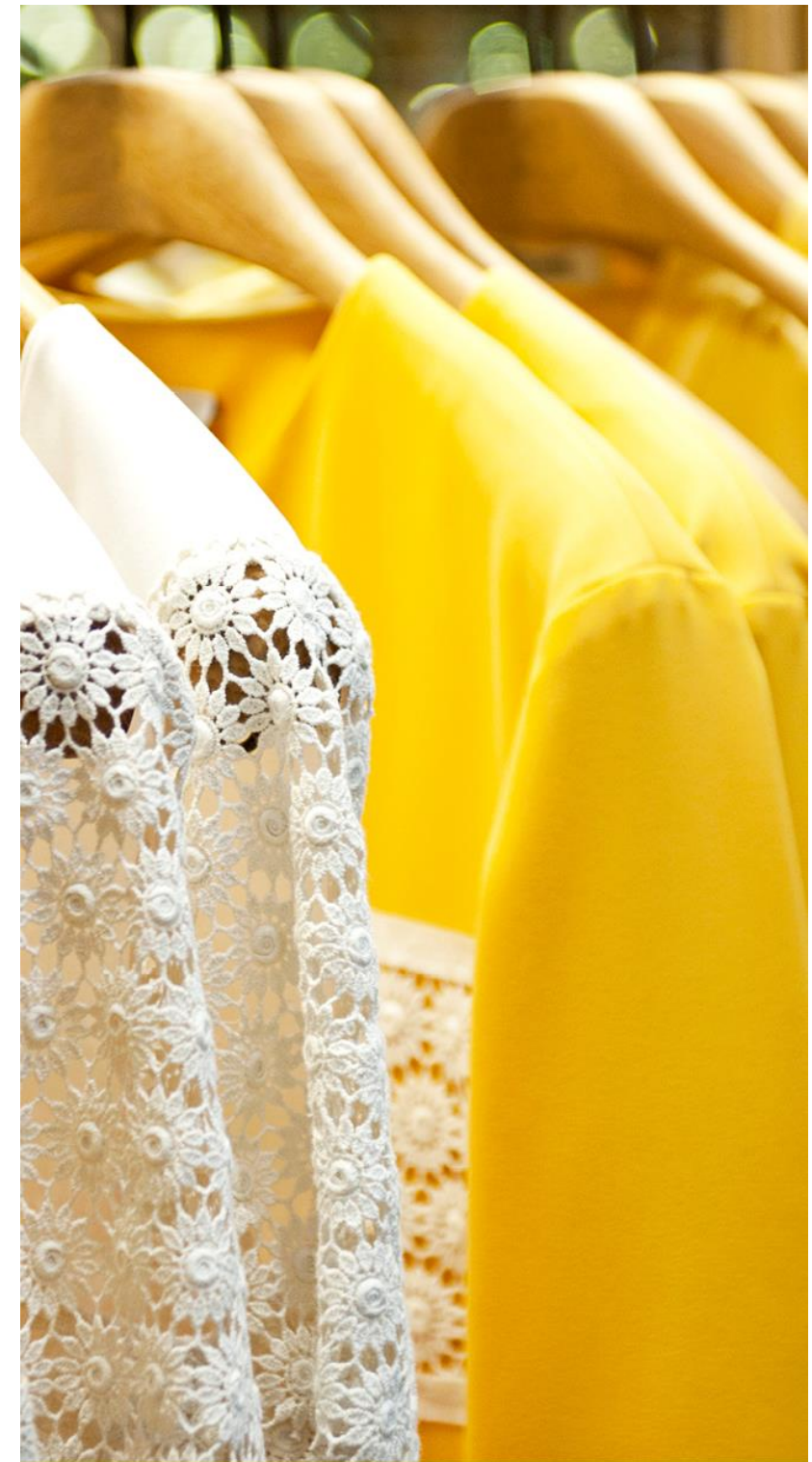
Key changes pursuant to the GPSR – safety assessment

1. Article 5a expands on the factors to be considered in an assessment of whether a product is safe, for example:
 - Connectivity / interconnection with other products (i.e. software)
 - The effect of software updates
 - The evolving, learning and predictive functionalities of a product (i.e. AI)
 - Risks to vulnerable customers such as children, older people, and persons with disabilities
 - The impact of different genders on health and safety and environmental risks
 - Cybersecurity features necessary to protect the product against external influences
 - New definition of 'risk' - the combination of the probability of an occurrence of a hazard causing harm and the degree of severity of that harm



Key changes pursuant to the GPSR – EU responsible person

2. The GPSR introduces the requirement for an economic operator to be established in the EU (e.g., a manufacturer, importer, or distributor)
 - This is currently only required for those products covered by EU harmonisation legislation e.g., The Toy Safety Directive
 - Economic operators will need to appoint a responsible person for products sold online and offline, whether they originate from the EU or from a third country
 - The responsible person will ensure that technical documentation, instructions, and safety information exist for the products they are responsible for
 - The product or its packaging/accompanying documentation will need to state economic operator's name, registered trade name (or trade mark), contact details including postal and electronic address



Key changes pursuant to the GPSR – technical file and modifications



3. The GPSR sets out new requirements for non-CE marked products to align with the requirements for CE marked products
 - For example, drawing up a technical file and keeping it updated and ensuring products bear type, batch, serial number
 - Internal risk assessments to prove the product's safety

4. There will also be a new requirement on substantial modifications so that responsibility for the safety of a product will lie with the person making the modification and considered "manufacturers" subject to the GPSR's obligations. A change will be "substantial" if it has an impact on the safety of the product i.e. software updates which may substantially change the original product and impact its safety

Key changes pursuant to the GPSR – online marketplaces

5. Article 20 introduces new obligations specifically for online marketplaces, for example:
 - They must designate a single point of contact in charge of product safety
 - They must know the traders on their platforms and the products they offer
 - They will have to make reasonable efforts to check randomly for dangerous products
 - Market surveillance authorities will be able to issue orders requiring online marketplaces to remove a dangerous product from their platform, to disable access to it, or display an explicit warning and they must receive / process the order and act without undue delay, and in any event within two working days from receipt of the order
 - Online marketplaces will have a separate obligation to notify the authorities "without undue delay" (i.e. immediately) if they are informed of any accident resulting in serious risk or actual damage to the health or safety of a consumer caused by a product sold on their marketplace

Key changes pursuant to the GPSR – recalls and remedies

6. The GPSR strengthens the rules on product recalls and safety warnings

- Manufacturers (or the responsible person if the manufacturer is not in the EU) will be obliged to report "an accident caused by a product" which has resulted in an individual's death or in serious adverse effects on their health and safety, permanent or temporary, including injuries, other damages to the body, illnesses, and chronic health effects "without undue delay from the moment they know about the accident"
- Reporting will be via the Safety Gate portal, which will also be used to notify product recalls. Consumers and other "interested parties" will also be able to use it to report products which may present a risk
- There will be a prescribed format for recall notices/template recall notice – see Article 34. They should avoid expressions that can decrease consumers' perception of risk (e.g., "voluntary", "precautionary", "in rare/specific situations")
- Consumers will be better protected in terms of the remedies available to them in the event of a product recall so that where possible, they will be able to choose from at least two of a repair, replacement, or refund (unless this would be impossible or disproportionate, in which case one remedy can be offered) – see Article 35

Key changes pursuant to the GPSR – collective redress



7. The GPSR amends the new EU Representative Actions Directive to allow class actions in respect of damage caused by an unsafe product, which will include breaches of the GPSR



8. Penalties for infringements of the GPSR will be left to the discretion of Member States but must be effective, proportionate, and dissuasive – see Article 40

How will the GPSR affect the UK? (1)

- The GPSR will not automatically be implemented in the UK because of Brexit
- The changes (if implemented) will apply to all manufacturers who sell products in the EU, so UK businesses placing products on the EU market will still be impacted
- The Office for Product Safety ("OPSS") is currently leading the government's consultation on changes to the current framework for product safety regulation in the UK. Call for evidence Nov 2021
- The OPSS focus is on consumer protection without stifling innovation and business growth
- It remains to be seen whether the UK will mirror the EU's proposals. The OPSS views the UK's departure from the EU as a "unique opportunity" to update the UK's product safety framework and diverge from the EU regime
- UK to maintain a global outlook, aligning with international practices to raise product quality and benefit trade
- Can expect similar proposals to expand products covered and alignment with modern business models

How will the GPSR affect the UK? (2)

- OPSS Call for Evidence focussed on the following:
 - product design, manufacture and placing on the market
 - new models of supply
 - new products and product lifecycles
 - enforcement considerations
 - a diverse and inclusive product safety framework.

What should you do now?

- Review and update risk assessments for products in light of revised safety assessment
- Consider preparing a technical file including e.g., instructions and safety information
- Plan and prepare for labelling changes to warnings and contact details
- Consider appointing a responsible person or Authorised Rep in the EU
- Review existing monitoring, traceability and recall systems in the case of defective products and consider updating and/or implementing entirely new systems to ensure compliance with new reporting requirements
- Review and update complaints procedures and internal registers
- Online marketplaces to review third party trader agreements and audit rights

