

# EU Product Safety Reform: A New Dawn Under Regulation (EU) 2023/988

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EU Product Safety Reform: A New Dawn Under Regulation (EU) 2023/988.....	1
About The Author.....	3
Unlocking Market Access.....	4
1. Introduction.....	6
2. Scope.....	7
3. Precautionary Principle.....	8
4. Aspects for Assessing the Safety of Products.....	9
5. Obligations of Economic Operators.....	10
Manufacturers.....	10
Internal Risk Analysis.....	10
Provision of Product Instructions.....	11
Internal Processes for Product Safety.....	11
Establishing an Economic Operator in the Union.....	11
Traceability.....	12
Manufacturers Selling by Distance (Including Online).....	13
Providers of Online Marketplaces.....	14
6. From RAPEX to Safety Gate.....	16
7. Enhanced Requirements for Market Surveillance Authorities.....	17
8. Application Date.....	18

## About The Author



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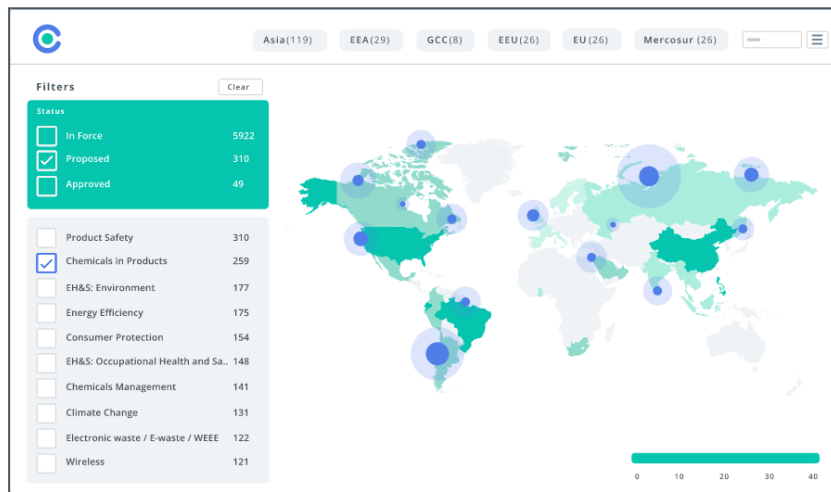
With over ten years expertise in global RoHS legislative and product safety conformity assessment requirements, Joyce also works closely with customers to assist them in understanding the implications of evolving regulation on their products.

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## 1. Introduction

EU institutions have agreed on and published the new [General Product Safety Regulation \(EU\) 2023/988 \(GPSR\)](#), some three years after instituting the regulatory fitness-check programme (REFIT) on the existing [General Product Safety Directive \(GPSD\)](#).

The agreed text, which represents a new age in the Union's regime for the protection of consumers from unsafe products, is a legal instrument apt for the digital age. Regulation (EU) 2023/988 is cognisant of the proliferation in the market of products enhanced by new technologies and hence new safety risks and also evolved business models in use by economic operators, most notably the recent rise in the dominance of e-commerce.

Increased obligations on economic operators in the non-harmonised sphere, greater scrutiny of the activities of online marketplaces and a vastly improved product recall system are all hallmarks of this new ambitious measure.

Further, this Regulation will ensure that provisions on market surveillance for non-harmonised products are fully in line with complimentary market surveillance rules for harmonised products or 'CE marked products', as recently updated through [Regulation \(EU\) 2019/1020](#).

What follows below is a review of the seminal aspects of the new Regulation, with a sharp focus on new requirements that do not exist under the GPSD. It does not however purport to offer a thorough analysis of all mandatory obligations.

Compliance implications for economic operators abound, and some organisational and financial preparation will inevitably be required in order to be sufficiently ready for the demands of this measure.

The new rules will enter into force on 12 June 2023 but will only apply, in the sense of creating binding legal effects, 18 months thereafter, on 13 December 2024.

## 2. Scope

The Regulation will apply, just as the GPSD does, to products intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them. This is the case whether the product is new, used, repaired or reconditioned.

Second-hand products or products that are repaired, reconditioned or recycled, that re-enter the supply chain in the course of a commercial activity, should be earmarked as within the remit of the rules, and also subjected to the same compliance processes as new products. Products for which the consumer cannot reasonably expect that they fulfil state-of-the art safety standards, such as products which are explicitly presented as to be repaired or to be reconditioned, or which are made available on the market as collectible items of historical significance, are however exempt.

In terms of scope, the most groundbreaking advancement in the Regulation is the inclusion of items whether interconnected or not to other items, thereby bringing digital products squarely within its scope, thus explicitly addressing the fact that new technologies, in particular Artificial Intelligence (AI), impact product safety.

The Regulation also introduces express itemisation of excluded products, as follows:

- (a) medicinal products for human or veterinary use;
- (b) food;
- (c) feed;
- (d) living plants and animals, genetically modified organisms and genetically modified microorganisms in contained use, as well as products of plants and animals relating directly to their future reproduction;
- (e) animal by-products and derived products
- (f) plant protection products;
- (g) equipment on which consumers ride or travel when that equipment is directly operated by a service provider within the context of a transport service provided to consumers and not operated by the consumers themselves;
- (h) aircraft referred to in point (d) of Article 2(3) of Regulation 2018/1139.

### 3. Precautionary Principle

The new Regulation arguably accords a more important status to the [precautionary principle](#) than is recognised under the GPSD, as it is not expressly limited to application by the competent authorities in the regulation.

As such, it is possible that in cases where the precautionary principle is invoked producers, manufacturers or importers will now be required to actively prove the absence of danger regarding a product placed on the market.



## 4. Aspects for Assessing the Safety of Products

The cardinal rule, now enunciated under Article 5, still holds: economic operators may only place or make available safe products on the Union market.

However, owing to an extension of the *necessary* elements to be taken into account when assessing if a product is safe the implications are, under the Regulation, more substantial for economic operators.

Unchanged factors are the characteristics of the product including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance and the effect on other products, where it is reasonably foreseeable that it will be used with other products.

The new Regulation will bring *two new factors* into play:

- (a) design and technical features of the product;
- (b) the effect on other products, where it is reasonably foreseeable that it will be used with other products, *including the interconnection of products among them.*

Operators will also need to involve considerations of the labelling of the product, with a focus on age suitability for children. Special attention should also be afforded to vulnerable categories of consumers such as children and older people, already mentioned under the GPSD, and now additionally persons with disabilities, as well as the impact of gender differences on health and safety.

## 5. Obligations of Economic Operators

### Manufacturers

#### Internal Risk Analysis

The Regulation will require manufacturers to carry out an internal risk analysis before placing products on the market.

Article 8 (4) governs the performance of this internal risk analysis and drawing up of technical documentation containing at least a general description of the product and its essential properties relevant for assessing its safety, before placing a product on the market.

This positive obligation will necessarily incur some financial expense on the part of manufacturers, and additionally call for the allocation of sufficient time for its fulfilment. In terms of the technical documentation, the following will need to be supplied:

- *at a minimum*: a general description of the product and its essential properties relevant for assessing its safety; and
- *additionally*, where appropriate, with regard to possible risks related to the product:
  - 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;
  - the list of the European standards referred to in Article 6(1) point a, or the other elements referred to in 6(1) point b or Article 7, applied to meet the general safety requirement laid down in Article 5.

The express requirement for technical documentation is consistent with existing stipulations under Union harmonisation legislation and those regarding traceability, now also coming under the general product safety regime, such as the obligation to keep the technical documentation for 10 years after the product has been placed on

the market, to ensure that the product bears a type, batch or serial number or other element allowing its identification and to indicate manufacturer contact information.

#### Provision of Product Instructions

Products not coming within the scope of Union harmonisation legislation will in future need to be accompanied by clear instructions and safety information in a language which can be easily understood by consumers. The language will be determined by the Member State in which the product is made available.

Instructions will not be mandatory where the product can be used safely and as intended by the manufacturer without such instructions and safety information.

#### Internal Processes for Product Safety

Another novel requirement in the Regulation comes under Article 13. Economic operators must have internal processes for product safety in place, allowing them to comply with the relevant requirements of this Regulation.

Those processes can be based upon organisational procedures, guidelines, standards, but in any case should be determined by economic operators themselves in relation to their role in the supply chain and the type of products concerned. Establishment and the format of the internal processes remains the sole responsibility of relevant economic operators.

#### Establishing an Economic Operator in the Union

Under Article 15(1) of the new Regulation, manufacturers must ensure there is an economic operator established in the Union.

The effect of this provision is essentially the extension of the obligation already set out in Article 4(1), (2) and (3) of [Regulation 2019/1020](#) to also cover products falling outside the scope of the Union harmonisation legislation, to ensure that there is a responsible economic operator established in the Union.

Products may therefore be placed on the market only if there is an economic operator established in the Union.

This party will fulfil the functions assigned under Article 4(3) of Regulation 2019/2010 and, additionally, be charged with regularly checking:

- (a) that the product complies with the technical documentation in accordance with Article 8 (4);
- (b) that the product complies with the requirements provided for in Article 8 (6) to (8) (product and manufacturer details, plus instructions).

Documented evidence of the checks performed must be made available to the market surveillance authorities upon request.

Insertion of this requirement will empower market surveillance authorities particularly in their task of tackling the sale of dangerous products online. Parties using online channels to supply substandard products to consumers will no longer be able to insulate themselves from legal repercussions owing to the lack of an economic operator or legal representative in the Union.

More costs will indeed be incurred in satisfying this requirement, and operators will be open to the risk of suit if their products do not comply with the European safety requirements.

### Traceability

The new regulation anticipates a system of traceability to which economic operators may need to adhere for certain products, categories or groups of products, which are susceptible to bear a serious risk to health and safety of consumers.

The Commission is empowered to give effect to this traceability requirement through delegated acts determining the products, categories or groups of products or components susceptible to bear a serious risk to health and safety of persons

specifying the type of data which economic operators shall collect and store by means of the traceability system, the means of display and of access to data.

Operators can be assured that adequate time would be afforded to them in order to prepare for these measures, if adopted.

### **Manufacturers Selling by Distance (Including Online)**

Special requirements will apply for products sold by distance, remarkably affecting future online sales. It should be noted that these requirements will apply to both non CE-marked and CE-marked products alike.

In essence, strict information requirements will be demanded of operators offering products through online channels, and the notification of accidents caused by such products without undue delay.

Offers for products shall clearly and visibly indicate at least the following information:

- (a) 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;
- (b) in case the manufacturer is not established in the Union, the name, postal and electronic address of the responsible person (i.e. party established within the Union);
- (c) information allowing the identification of the product, including a picture of it, its type and any other product identifier;
- (d) any warning or safety information that is to be affixed on the product or on the packaging or an accompanying document in a language which can be easily understood by consumers.

Accident notifications or reports must be made by the manufacturer, or the responsible person, as soon as they become aware, through the [Safety Business Gateway](#) (formerly RAPEX).

Importers and distributors should also make their own reports upon learning of the accident, to the manufacturer, who may proceed with the notification to Safety Gateway or direct the importer/distributor to complete this requirement.

### **Providers of Online Marketplaces**

The combined effect of Regulation (EU) 2022/2065, the '[Digital Services Act](#)', and Regulation (EU) 2023/988 will mean that providers of online marketplaces will see a marked increase in the scrutiny of their activities under the new Regulation, and will be subject to new due diligence obligations. Requirements will apply equally to products covered by Union harmonised legislation and those which are not.

Given the difficulties experienced by state market surveillance authorities in checking the conformity of products offered for sale online and ensuring compliance with the established requirements.

Under the Digital Services Act, scheduled to apply from 17 February 2024, online marketplaces are directed to make 'reasonable efforts' to conduct random checks on products that are already on the market against any existing database. The GPSR would alter this provision to mandate the use of [Safety Gate](#), a complete EU-wide system for non-food dangerous products, for performing such checks.

Providers of online marketplaces will also need to designate a single point of contact allowing for direct communication, by electronic means, with Member States' market surveillance authorities. This may be seen as a leveling of the playing field with their counterparts selling offline.

And, pursuant to Article 22(3), providers of online marketplaces are also subject to the requirement to have internal processes for product safety in place in order to comply without undue delay with the relevant requirements of the Regulation. In particular, the processes should enable traders to provide information regarding product safety including information on the manufacturer established in the Union or, where applicable, the responsible person, and the trader's self-certification committing to

offer only products that comply with this Regulation and additional identification information, in accordance with Article 30(1) of the Digital Services Act.

If an online vendor is requested by a state market surveillance authority to take down a product because it is unsafe, that order will apply to all identical products.

Meanwhile, a number of online marketplaces have reconfirmed their dedication to taking measures that go beyond the legal requirements by signing the revised version of the original Product Safety Pledge, the [Product Safety Pledge +](#). Commitments regarding products sold online on their interfaces include a strengthened notice and takedown mechanism, proactive monitoring of recall sites such as the EU [Safety Gate](#) and additional commitments linked to recalls, transparency or trader education, and a modernised reporting mechanism.

Signatories will start applying the new measures as of 1 December 2023, and therefore will take action ahead of the tightened obligations coming under the Regulation.

## 6. From RAPEX to Safety Gate

RAPEX, the alert system for information exchange regarding unsafe consumer products established under the GPSD, is officially renamed under Regulation (EU) 2023/988 as Safety Gate.

Under the revamped safety regime, the Safety Gate will comprise three elements:

1. *Safety Gate Rapid Alert System*: alert system on dangerous non-food products whereby national authorities and the Commission can exchange information on such products;
2. *Safety Gate Portal*: a web portal to inform the public and enable them to submit complaints;
3. *Safety Business Gateway*: a web portal to enable businesses to comply with their obligation to inform authorities and consumers of dangerous products and accidents.

This system will apply equally to products covered by Union harmonised legislation, which already use RAPEX, and those not. Interfaces will exist between the different Safety Gate elements.

Economic operators and providers of online marketplaces will be subjected to heightened obligations regarding product recall. For example, economic operators and providers of online marketplaces will be obliged to use any customer data already at their disposal to inform consumers of recalls and safety warnings. As such the current practice of just publishing recalls on websites, in newspapers, etc. will no longer be viewed as satisfactory.

Whenever a consumer is requested to provide contact information at purchase, they must be directly informed thereafter, using this information, if a product is being recalled. These targeted recalls should not however prevent economic operators and providers of online marketplaces from making all customers aware of a product recall notice, nor from offering remedies to other end-users.



## 7. Enhanced Requirements for Market Surveillance Authorities

Market surveillance authorities will be more proactively involved in the safety of products on the market, with extended powers under Article 31 and 32.

The Commission shall organise on a regular basis joint activities of market surveillance authorities whereby the market surveillance authorities conduct inspections regarding products offered online or offline, which those authorities acquired under a cover identity. (so-called 'mystery shopping').

The regulation also mandates simultaneous coordinated control actions (or 'sweeps') of particular products or categories of products with the objective of identifying breaches of EU law.

## 8. Application Date

As a Regulation, the measure must be directly applied in its entirety across the EU, and Member States will not be required to enact transposing national legislation.

As a result, a more consistent and robust regulatory framework, which is not undermined by divergent domestic provisions, can be expected to emerge, bringing product safety protections in the European Union to a new enhanced level.

Companies can expect an increase in their compliance burden when this Regulation becomes enforceable, and prompt attention should therefore be paid to getting their house in order to meet its increased demands.