

EU Regulation 2023\988 on the general safety of consumer products placed on the EU market

In recent years, Europe has stepped up efforts to ensure the safety of products placed on its vast market. A key pillar in this direction is EU Regulation 2023/988 of May 10, 2023 on general product safety (“Regulation”).

The Regulation, which will be applicable from December 13, 2024 in all EU countries, strengthens the tools already provided by EEC Directive No. 95 of 2001, which is being repealed.

The framework of the Regulation is consistent with that of Regulation 2010/2019 on the supervision and conformity of products covered by the so-called “harmonization legislation” of the Union, which includes machinery and a diverse set of items intended for industry or assembly into more complex products.

The general obligation to place safe products on the market

The Regulations provide a general obligation for all economic operators belonging to the production and distribution chain to place only “safe products” on the market.

The products covered by the Regulation are both those intended for consumers and those for which consumer use can reasonably be expected.

The general safety obligation applies to any product sold or given away free of charge, including in the context of providing a service, and extends to used, repaired and reconditioned products. Exceptions are food products, medicines and other items specifically listed in the Regulations.

A significant change is the application of the Regulation also to online sales, where the offer is intended for consumers in the Union; this occurs when the trader directs, by any means, its activities to one or more Member States. Uniformity of application to consumer products throughout the Union market is thus guaranteed, without distinction between the “physical” market and the online market.

The concept of “safe product”

Compared with the previous regulations, the definition of “safe product” is expanded and updated. It is considered as such only that which does not present risks or presents minimal risks, compatible with its use.

For this purpose, its characteristics, packaging, its interaction with other products, labelling, and the categories of consumers for whom it is intended are to be considered (to give just a few examples), but also its nature, the possibility that particular categories of consumers - such as minors and the elderly - may come into contact with it, and, where relevant, its degree of protection from cyber risk and its evolutionary, learning, and predictive capabilities.

Any unsafe product is considered “dangerous”.

Obligations of the manufacturer

The manufacturer must ensure that, when the product is placed on the EU market, it is designed and manufactured in compliance with the general safety obligation. Any operator who places the product on the market under his own name and/or trademark is treated as the manufacturer.

Similarly, an operator who carries out a substantial transformation of the product that alters it in a way not envisaged in the risk assessment carried out by the manufacturer, altering the risks associated with it, is considered a manufacturer.

Manufacturers may appoint by written deed an authorized representative in order to delegate to them some of the activities incumbent on them and make them the point of contact with the national Supervisory Authority.

Risk assessment

From an operational point of view, the Regulation introduces an obligation for manufacturers to conduct a documented risk assessment before placing the product on the Union market. This analysis includes identification of potential hazards, assessment of the severity of the risks, and implementation of appropriate mitigation measures.

Product traceability and information

The Regulation has, in addition, introduced measures to establish a more effective traceability system, consisting of the collection and storage of data that enable the identification of the product, its components and the economic operators involved in its supply chain.

In fact, the product must bear a number of mandatory information such as: name, trade name, traders' e-mail address, type number, batch, instructions and information in a language understandable by consumers.

Manufacturers are also required to establish communication channels designated to collect safety-related reports and to establish an internal register of complaints.

Obligations of the importer

The importer is under a general obligation to ensure the safety of the product and may not place it on the market if he or she has reason to believe that it is unsafe. The importer is also required to ensure that the product is accompanied by safety instructions in the language of the importing country.

The importer's name or trademark and contact information must be affixed to the product or its wrapping or packaging.

Obligations of the distributor

The distributor is obliged to ensure that the products bear the information and indications required to be borne by the manufacturer or importer. In addition, he or she must ensure that storage and transportation conditions do not compromise the safety condition of the products.

Suppliers of online marketplaces

Online marketplace providers are subject to specific and considerable obligations. First and foremost, they must designate a single point of contact for direct communication with Member State supervisors.

These operators may be subject to specific measures by the Supervisory Authority, such as an order to remove a particular product from their online interface, to disable access to it, or to display an explicit warning about it.

Operators are also required to conform their marketplaces in such a way as to allow sellers to display the essential product information required by the Regulations, including safety instructions.

A significant burden on online marketplaces is to inform those who have purchased through their platform a recalled product of which they are aware. This possibility must, of course, also be managed from the perspective of consumer data management and related governance. In addition, the online marketplace provider may also decide to remove the offering of a dangerous product, or disable access to it by users. These are eventualities that should be regulated in marketplace agreements.

Cooperation among economic operators and with the Supervisory Authority

The Regulations provide for a regime of cooperation among economic operators, and between them and the Supervisory Authority.

In fact, all operators who are part of the production and distribution chain of a product that is found to be unsafe are required to inform the Supervisory Authority through the Business Safety Gateway and to coordinate with each other in order to provide the necessary information and corrective actions in a timely manner, including to consumers.

It is provided, for example, that the importer, if he or she has reason to believe that a product is unsafe, must inform the manufacturer, relevant supervisory authorities and consumers through the Business Gateway. In the case of a product being recalled, or where it is necessary to give consumers a safety warning, the importer must cooperate with other operators so that all consumers who may be affected are informed without delay. Again, the Regulations expressly provide for the possibility of using personal data collected by operators.

If not all affected consumers can be contacted, the Regulations set out a requirement to use notices on social media, websites or other appropriate channels.

Product recalls and remedies for consumers

One of the most important corrective actions is the recall. In this regard, the Regulations establish what content it should have: from the title to instructions on the actions to be taken by consumers, to the contact details to be given to the remedies available to the consumer affected by the recall.

In this last regard, the Regulations state that in the event of a recall, the consumer shall have the choice between the repair or replacement of the product or an adequate refund (at least equal to the price), without prejudice to the economic operator's right to offer further remedies. Remedies may be limited if some of them would impose disproportionate efforts.

Penalties

With regard to sanctions, the Regulation has left it to the Member States to provide for measures to be applied in case of violation of obligations by economic operators.

Conclusions

A review of the Regulations reveals the importance of cohesion among operators in the distribution chain in order to ensure product safety.

The cooperation obligations placed on all economic operators, both among themselves and with the Supervisory Authorities, tend to avoid any possible "gray area" regarding safety responsibilities.

Indeed, in the system outlined by the Regulations, operators are encouraged to take a proactive attitude aimed at verifying compliance with obligations by those ahead of them in the distribution chain.

Remarkable, too, are the interrelationships with data protection legislation and attention to technological developments, as reflected not only in the definition of product risks, but also in the focus on the online sales sector including marketplaces.

Compliance with the Regulation will require all operators to adopt internal procedures capable of effectively coping not only with the obligations imposed on them in terms of security and accountability, but also with the need for coordination with other operators in the supply chain of a given product.

For this need to be met, it will be appropriate to regulate relationships with partners in a way that makes their respective obligations explicit, for example in supply contracts or - in the case of online marketplace providers - those of marketplaces.