Regulation on general product safety: ***what you need to know***

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2024 was a particularly eventful year in terms of European regulations on consumer goods. Besides the adoption of several important regulations, like the New Directive on liability for defective products (Directive (EU) 2024/2853) of 23 October 2024 or the Regulation laying down harmonised rules on artificial intelligence (Regulation (EU) 2024/1689) of 13 June 2024, the Regulation on general product safety of 10 May 2023 (Regulation (EU) 2023/988, hereinafter ,**"the Regulation"**) came into effect on 13 December 2024. This Regulation repeals Directive 2001/95/EC (hereinafter, **"the Directive"** and applies to products placed on the European market since 13 December 2024.

Contrary to other regulations on which we recently commented[1] , this Regulation might be less innovative, but is nevertheless still crucial. Therefore, an exhaustive and practical presentation is required for companies to fully understand the extent of their obligations.

This Regulation hence ought to be examined in three steps:

- The first step will explain the scope of application of the Regulation as well as its main purpose, which is to guarantee the general safety of products placed on the European market (**1**);
- The second step will detail the main obligations of all economic operators who can place a product on the market or make a product available on the market (**2**); and
- The third step will present the different powers and obligations in terms of market surveillance, for member States, national and European authorities, as well as consumer rights, notably in the event of a product recall (**3**).

1. PURPOSE: GENERAL SAFETY OF PRODUCTS

Article 5 of the Regulation indicates that: "Economic operators shall place or make available on the market only safe products".

As a reminder, a "safe product" is defined as: "any product which, under normal or reasonably foreseeable conditions of use, including the actual duration of use, does not present any risk or only the minimum risks compatible with the product's use, considered acceptable and consistent with a high level of protection of the health and safety of consumers".

A dangerous product is an "unsafe" product.

Therefore, the main purpose of this Regulation is to ensure that all products placed on the European market comply with the "essential safety rules" applicable to all consumer goods[2] (**1.2**). However, this implies that the Regulation be subsidiary to other more specific texts, which also lay down rules on the safety of products to which they apply (**1.1**).

[1] See our article on New Directive (EU) 2024/2853 of 23 October 2024 on liability for defective products: https://www.signaturelitigation.com/wp-content/uploads/2024/09/Whats-likely-to-come_-v.04.pdf.

[2] Nevertheless, some products are excluded from the scope of application of the Regulation (Article 2.2), including medicinal products; food; living plants and animals; plant protection products; etc.

1.1 A subsidiary scope of application

Article 2.1 of the Regulation explains that it is applicable only in the absence of more specific European texts that would specifically govern some types of products.

Therefore, the provisions of the Regulation are only applicable to products placed on the European market that would not already fall under the scope of application of a specific European text, or to the risks that are not covered, for these products, by special texts.

The purpose of the Regulation is to bring a general framework for the safety of the products on the European market, without prejudice to more detailed and specific rules.

For instance, when a product is governed by another European text and complies with the safety provisions stated in that text, the product will be considered "safe" within the meaning of the Regulation (Article 7). This is the direct expression of the general and subsidiary application of the Regulation.

Furthermore, the Regulation complements the Regulation on market surveillance and compliance of products of 20 June 2019 (Regulation EU 2019/1020) (hereinafter, the "**Regulation on Market Surveillance**").

Consequently, the Regulation has a general and subsidiary scope and defines the minimum standard that should be applicable for the safety of products in the European Union (EU).

1.2 An updated minimum standard to assess the safety of products

This standard is defined in Article 6 of the Regulation, which lists the elements that notably contribute to the assessment of the safety of products.

First of all, it ought to be noted that the Regulation is aligned with other European texts on the safety of products but was not harmonised or made consistent with these different applicable texts.

Indeed, the Regulation is characterised by the objective of adapting to new technologies by including new products and developing the assessment criteria of their safety.

Article 3.1 defines the term "product" as: "*any item, whether or not it is interconnected 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*".

And Article 6 notably specifies that: *"When assessing whether a product is a safe product, the following aspects in particular shall be taken into account:*

(a) [...];

(b) the effect on other products, where it is reasonably foreseeable that the product will be used with other products, including the interconnection of those products;

(c) the effect that other products might have on the product to be assessed, where it is reasonably foreseeable that other products will be used with that product, including the effect of non-embedded items that are meant to determine, change or complete the way the product to be assessed works, which has to be taken into consideration when assessing the safety of the product to be assessed;

[...]

(g) when required by the nature of the product, the appropriate cybersecurity features necessary to protect the product against external influences, including malicious third parties, where such an influence might have an impact on the safety of the product, including the possible loss of interconnection;

(h) when required by the nature of the product, the evolving, learning and predictive functionalities of the product.

These new criteria show the objective of the Regulation to take into account technological and technical progress regarding consumer goods, and to be in line with the general dynamic of revising European laws[3].

Then, Article 6 also defines other more regular criteria such as the product's characteristics of the product, its presentation, or appearance, as well as the categories of consumers using the product, etc.

However, in comparison to the Directive[4], the Regulation also modernises these criteria. In particular, regarding the categories of consumers using the product, the Regulation now takes into consideration persons with disabilities as well as gender differences to assess health and safety risks for consumers (Article 6.e). We also notice the reinforced protection of children, particularly when a product not initially designed to be used by children might have an appearance similar to a product that is generally used by children (Article 6.f.ii).

When the product is not considered safe pursuant to Article 7, i.e. when the product is not subject to the safety standards set by another more specific text, other international or national standards can be taken into account to assess the safety of the product (Article 8), including, for instance, voluntary certification schemes, codes of good practice, the current state of the art and technology, etc.

Lastly, still with the aim of modernising the law, it is interesting to note that the Regulation also takes into account the influence of online selling on the principle of making products available on the European market (Article 4). Making a product available is defined as the *"supply of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge"*.

Yet, the Regulation considers that *"products offered for sale online or through other means of distance sales shall be deemed to be made available on the market if the offer is targeted at consumers in the Union. An offer for sale shall be considered to be targeted at consumers in the Union if the relevant economic operator directs, by any means, its activities to one or more Member States"*. Surprisingly, the Regulation here refers to a principle of private international law that is applicable to conflicts of laws and jurisdiction[5]. This concept should hence be construed in line with the other European texts that are using it, although its assessment is rather complex and usually casuistic.

Any product placed on the European market and covered by the Regulation should therefore present the minimum level of safety which assessment is possible pursuant to Article 6, on the basis of modernised criteria to take into consideration recent technological progress and guarantee consistency with the revision of other important European texts applicable to the products.

2. ECONOMIC OPERATORS' OBLIGATIONS

In addition to laying down essential and minimum rules applicable to product safety on the European market, the Regulation also covers the obligations of the entire distribution chain, unlike the Directive that only dedicated referred to "producers" and "distributors". This is consistent with the objectives of harmonising legislation in the EU.

First of all, the Regulation establishes that there must be, in the EU territory, an economic operator responsible for the general safety of the products for such products to be placed on the European market (Article 16). This person can be the manufacturer, importer or distributor of the product (Article 3.13).

Therefore, in accordance with the Regulation on market surveillance (Article 4.3), this Regulation provides that any person responsible for the declaration of conformity, as well as cooperating with and informing competent authorities regarding the conformity of products, is defined as the economic operator responsible for the general safety of the products placed on the market. They must notably ensure that the product is complies with its technical documentation and that instructions and safety information are available. They are hence not responsible for all the obligations applicable to all economic operators, but are the main interlocutor in the EU to guarantee the safety of the products placed on the market. Each economic operator has their own obligations.

[3] See our article on New Directive (EU) 2024/2853 of 23 October 2024 on liability for defective products [https://www.signaturelitigation.com/wp-content/uploads/2024/09/Whats-likely-to-come_-v.04.pdf].

[4] See Article 2 (b) of the Directive.

[5] See Article 17 of Regulation (EU) 1215/2012 of 12 December 2012, called "Brussels I bis", and Article 6 of Regulation 539/2008 of 17 June 2008, called "Rome I".

The identification information of the economic operator defined above must appear on the product, its packaging or, failing such, in the documentation provided with the product (Article 16.3).

The Regulation hence provides for specific obligations for each level of the products' distribution chain: from the manufacturer to the provider of online marketplace (**2.1**), as well as general obligations that are equally applicable to all economic operators (**2.2**).

2.1 Specific obligations for each level of the distribution chain

The Regulation provides for the obligations applicable to the manufacturers (**a**), importers (**b**), distributors (**c**) as well as providers of online marketplaces (**d**).

a) The manufacturer

The manufacturer is defined as "any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under that person's name or trademark" (Article 3.8). Their obligations are defined in Article 9.

The manufacturer can appoint an authorised representative to represent them in the EU and transfer all or part of their obligations (Article 10).

Any person who substantially modifies the product, after it was placed on the market, is considered as the manufacturer of a new product and is subject to the obligations applicable to the manufacturer as of the substantial modification (Article 13). A substantial modification is a modification that has an impact on the safety of the product, either due to the creation of a new hazard or the increase of the level of risk, and that changes the product in a manner that was not foreseen in the initial assessment of the risks. The modifications must not have been made by the consumers themselves for their own use.

The manufacturer's essential obligation is to design and place on the market products that are safe, within the meaning of Article 5. The manufacturer must notably carry out an internal analysis of the risks of the product and then establish technical documentation containing at least a general description of the product and its essential characteristics relevant for assessing its safety by the other levels of the distribution chain, the case arising (Article 9.2). They must keep this technical documentation for 10 years from the date when the product was placed on the market, and make it available for the surveillance authority.

This obligation did not exist in the former system of the Directive (Article 5).

The manufacturer must also indicate their name on the product, the packaging or, failing such, in the documentation provided with the product (Article 9.6).

They must also ensure that the product is provided with clear instructions and safety information for the consumer, unless they consider that it is not required to guarantee the safe use of the product by the consumer (Article 9.7). These instructions must be written in a language that can be easily understood by the consumer depending on the Member State in which the product is made available on the market.

It ought to be noted that the information that needs to be communicated to the consumer by the manufacturer can also be transmitted in a digital format via electronic technical solutions that are clearly identifiable on the product (e.g. a QR code[6]). This digital format alone is not sufficient, but it could allow the manufacturer to only provide key elements or to shorten the information on the product/packaging and invite the consumer to refer to an external digital link for further details. It will be interesting to see how this option will be applied.

Once the product is placed on the market, the manufacturer must still meet several obligations. For instance, the manufacturer must ensure that the products placed on the market remain safe. They provide consumers with communication channels enabling them to share their complaints regarding the safety of the product (Article 9.11). The manufacturer must record all the complaints received and their answers within an internal register (Article 9.12).

[6] See Recital 32 of the Regulation

When the manufacturer, through complaints or by any other means, is made aware of or has reason to believe that a product they placed on the market is dangerous, they immediately proceed as follows:

- They take the necessary corrective measures to bring the product into conformity, including withdrawing the product from sale or recalling it;

- They inform the consumers pursuant to the rules provided for in the Regulation (see **2.2.a**);

- They inform the market surveillance authorities of the relevant Member States pursuant to the rules provided for in the Regulation (see **2.2.b**).

b) The importer

The importer is defined as "any natural or legal person established within the Union who places a product from a third country on the Union market" (Article 3.10).

The obligations of the importer of the products onto the European market are defined by Article 11 and mainly aim at ensuring that the obligations of the manufacturer were indeed complied with. It is a second level of surveillance and guarantee of product safety before they are made available on the European market.

The importer who notices that a product does not meet the safety requirements imposed on the manufacturer cannot place the product on the European market (Article 11.2).

The importer indicates their name on the product, packaging or, failing such, in a document accompanying the product (Article 11.3).

They must keep a copy of the technical documentation established by the manufacturer and make it available for the surveillance authority for 10 years from the date on which the product was placed on the market (Article 11.6).

When an importer, based on information at their disposal, considers or has reasons to believe that a product they placed on the market is dangerous, they must immediately:

- Inform the manufacturer;

- Ensure that the necessary corrective measures are implemented by the manufacturer, or implement them directly;

- Ensure that consumers are informed;

- Inform the market surveillance authorities of Member States in which the products were made available.

Some of the importer's obligations are hence subsidiary to the manufacturers' obligations. The importer must guarantee that the manufacturer indeed complied with their obligations, and if not, implement them or decide not to place the products on the market.

c) The distributor

The distributor is defined as "any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market" (Article 3.11).

The obligations of the distributor are defined in Article 12 of the Regulation. The distributor acts as a third level of guarantee for product safety. They are in charge of ensuring that the manufacturer and the importer, if applicable, have complied with their obligations before placing the product on the market.

If a distributor, based on the information at their disposal, considers or has reason to believe that a product they placed on the market is dangerous or that it is not compliant with the manufacturer's and/or importer's obligations, they must:

- Immediately inform the manufacturer and/or importer;

- Ensure that the necessary corrective measures are implemented;

- Ensure that the market surveillance authorities of the Member States in which the product was made available on the market are immediately informed.

Therefore, the obligations of the distributor are even more subsidiary than the importers. In particular, it is not strictly mandatory for the distributor to replace the manufacturer, unless they are appointed as the economic operator responsible for the general safety of the product within the meaning of Article 16 of the Regulation. They must only ensure that the two previous levels of the chain comply with their obligations or cooperate with the market surveillance authority the case arising.

d) The provider of an online marketplace

One of the new features of this Regulation is the integration of online marketplace providers amongst the distribution chain of the products on the European market. This addition is consistent with the other European texts, and in particular the Regulation of 19 October 2022 on a single market for digital services (Regulation (EU) 2022/2065) (hereinafter, "the Regulation on Digital Services") that is applicable since 17 February 2024. Therefore, the Regulation applies without prejudice to the Regulation on Digital Services.

The provider of an online marketplace is defined as "a provider of an intermediary service using an online interface which allows consumers to conclude distance contracts with traders for the sale of products" (Article 3.14).

The obligations of providers of online marketplaces (hereinafter, "marketplaces") are defined in Article 22 of the Regulation. Unlike manufacturers, importers or distributors, marketplaces are not economic operators, unless they act as such. They hence have their own specific and separate obligations.

They designate a single point of contact allowing for direct communication, by electronic means, with the market surveillance authorities of the Member States relating to product safety (Article 22.1). They also designate a single point of contact allowing consumers to directly and quickly reach them regarding product safety (Article 22.2).

Marketplaces register on the Safety Gate portal, the operation of which will be described below (see 3.2).

Marketplaces implement internal processes for product safety to perform their obligations "without undue delay" (Article 22.3). In particular, these processes must enable them to answer to surveillance authorities' requests relating to the withdrawal or restriction of the access to an offer for a dangerous product "without undue delay" and, in any case, within two working days from receipt of the order (Article 22.4). The order is issued pursuant to the powers conferred on the surveillance authorities in accordance with Article 14 of the Regulation on Market Surveillance and with the minimum conditions of Article 9.2 of the Regulation on Digital Services.

Orders must allow marketplaces to proportionally identify the concerned products, without checking each product one by one, but rather by using "reliable automated tools" (Article 22.5). Therefore, marketplaces must be able to only refer to the information communicated in the order to identify the products which withdrawal is required.

Additionally, marketplaces must stay informed of products that were declared dangerous by surveillance authorities or by consumers (Article 22.6). They must process without undue delay, and in any case within three working days from receipt, notices on product safety received in accordance with Article 16 of the Regulation on Digital Services (Article 22.8).

Furthermore, marketplaces must organise their interface in a way that enables operators offering the product to provide the essential information on the product, in an easily accessible manner. This information must include at least: the identification information of the manufacturer, the identification information of the responsible operator within the meaning of Article 16 of this Regulation, the case arising, the information on the product and any warning regarding safety (Article 22.9).

They must send to the operators placing products on their marketplaces any information on the safety of their products. They must cooperate with market surveillance authorities and, notably, guarantee access to their interfaces by the authorities (Article 22.12).

In the event of a recall of dangerous products, marketplaces must ensure to provide consumers with relevant information, in due course, by directly contacting them and publishing information on the recall on their interfaces (Article 22.12).

Lastly, marketplaces must suspend their services to economic operators who regularly offer products that are not compliant with the Regulation, after issuing a warning, and at least for a reasonable period of time (Article 22.11). This obligation refers to Article 23 of the Regulation on Digital Services and must be identically interpreted and applied.

2.2 General obligations for all economic operators

The Regulation provides for general obligations that equally apply to all economic operators within the meaning of Article 3.13, and especially to the operator designated as being responsible for the general safety of the products in the European Union within the meaning of Article 16, which should exclude marketplaces (a). Other obligations are mainly imposed on the manufacturer, but extend to other operators on a subsidiary basis, especially if the manufacturer is not settled in the EU (b).

a) General obligations of economic operators

Pursuant to Article 14 of the Regulation, economic operators must implement internal processes related to product safety enabling them to comply with the relevant requirements of this Regulation.

Furthermore, pursuant to Article 15, all economic operators must cooperate with market surveillance authorities to send information on products or to participate in the elimination or mitigation of the risks that the products can present.

In addition, in accordance with Article 19 of the Regulation, the economic operators placing products on the online marketplace or using other distance selling means must indicate a certain number of mandatory information, including the identification of the manufacturer, of the operator responsible for the general safety of the products in the EU, and the identification and safety information of the product.

Lastly, in the event of a product recall or certain safety warnings, each economic operator is required to inform the consumers to guarantee the safe use of the product (Article 35). This obligation also applies to marketplaces. The idea is that consumers must, based on the information each economic operator and marketplace has, be directly informed of the recall without undue delay. For instance, operators and marketplaces must use the personal data they collect to personally inform each consumer.

Also, if all concerned consumers cannot be individually informed of the recall or safety warning, operators and marketplaces must send information on this recall or safety warning through other appropriate and generalised communication channels, such as their own website, social media, retail outlets or announcements in mass media (Article 35.4). This information must be accessible to persons with disabilities.

Specifically regarding product recalls, Article 36 of the Regulation provides for rules regarding form that need to be complied with[7], which represents a major addition compared to the Directive (see Annex). The product recall notification must be written. It must be easily understandable by consumers and available in all the languages of the Member States in which the product was placed on the market. It must include at least the following elements:

- A specific headline as follows: "Product safety recall";

- A clear description of the product, including a picture, its name and brand, the identification numbers, the places where the product was sold;

- A description of the hazard avoiding any element likely to decrease the consumers' perception of the risk;

- A clear description of the measures the consumers must take;

[7] See, in particular, an example of recall notice established by the European Commission and annexed to the Implementing Regulation (EU) 2024/1435 of 24 May

- A description of the remedies available to consumers;

- A free phone number or interactive online service enabling consumers to get more information on the recall;

- Encouragement to share information related to the recall.

b) Manufacturers' obligations extended to other operators: information of market surveillance authorities via the Safety Business Gateway

Other obligations mainly apply to manufacturers but can also extend to other economic operators, on a subsidiary basis, when the manufacturer is not settled in the EU, and notably to the responsible operator within the meaning of Article 16 of the Regulation.

In particular, in accordance with Article 9.8 of the Regulation, manufacturers must inform the market surveillance authorities of the Member States in which the dangerous product was placed on the market. This information is formalised and must be communicated via the Safety Business Gateway.

The Safety Business Gateway is an online interface where economic operators and marketplaces can inform market surveillance authorities in the event of dangerous products and send the required information to process these warnings (Article 27). It is hence a communication interface dedicated to professionals and surveillance authorities.

This obligation extends to importers if they notice, in particular, that the manufacturer did not comply with their obligations and did not send all the information related to a dangerous product via the Safety Business Gateway (Article 11.8). Distributors do not have a strict obligation to replace the manufacturer or importer in case of failure, but they must ensure that the information is sent to the surveillance authorities via the Safety Business Gateway (Article 12.4). However, if the distributor is the responsible operator within the meaning of Article 16 of the Regulation, the declaration obligation via the Safety Business Gateway should be applicable to them.

This is expressly provided for in the case of accidents related to product safety (Article 20). Indeed, the obligation to inform market surveillance authorities via the Safety Business Gateway is applicable as soon as there are reasons to believe that a product is dangerous. A dangerous product is not necessarily a product that caused an accident. It is a product presenting a risk that cannot be ignored when it comes to the health and safety of the consumers (Article 3.2 a contrario). However, when the dangerous product caused an accident, the obligation to inform is particularly governed (Article 20). The manufacturer remains the main party responsible for the notification of the accident to the market surveillance authorities through the Safety Business Gateway. Yet, when the latter is not established in the EU, this obligation is transferred to the responsible operator within the meaning of Article 16 of the Regulation (Article 20.4) (i.e. usually the importer or the distributor of the product). In any case, the manufacturer can instruct the importer or distributor of the product that caused the accident to notify it (Article 20.3).

Economic operators and marketplaces are not the only parties in charge of market surveillance, and other parties can intervene to guarantee the safety of the products placed on the European market.

3. MARKET SURVEILLANCE

The last section of the Regulation concerns the rights and obligations of other stakeholders of the safety of the European market: market surveillance authorities (**3.1**), Member States and European institutions (**3.2**) and consumers (**3.3**).

3.1 Market surveillance by national authorities

Once again, it is necessary to refer to the Regulation on Market Surveillance. Indeed, this Regulation determines the organisation and powers of the market surveillance authorities designated by the Member States. Therefore, within the meaning of Article 11 of this Regulation, market surveillance authorities must ensure that the products placed on their internal market are safe by notably carrying out inspections (Article 14) and ensure that economic operators comply with their obligations and implement the necessary corrective measures in the event of hazardous products; or to replace these operators in case of failure.

These authorities must exercise their powers independently, impartially and without bias.

In addition to the prerogatives conferred on these authorities pursuant to the Regulation on Market Surveillance, this Regulation also provides that these authorities can coordinate their activities using a network dedicated to consumer safety (Article 30) and agree on joint activities on product safety (Article 31). The main purpose of the network is to facilitate the exchange of information and expertise between authorities. The main objective of the joint activities is to allow all the authorities of the Member States involved therein to share their efforts to inspect and assess the conformity of products from specific categories at the European scale.

Therefore, Article 32 of the Regulation specifically provides for the possibility for market surveillance authorities to coordinate their efforts to conduct simultaneous inspections referred to as "sweeps". These actions are coordinated by the European Commission.

3.2 Market surveillance by Member States

Beyond the powers of market surveillance authorities, Member States have their own obligations as per the Regulation (Article 26). Indeed, Member States must assess the risk presented by a hazardous product based on the notifications submitted by economic operators or marketplaces through the Safety Business Gateway and determine whether it is necessary to warn European institutions and other Member States through the Safety Gate Rapid Alert System (hereinafter, "Safety Gate").

The Safety Gate is an interface similar to the Safety Business Gateway for the communication of information on the risks and accidents related to a product placed on the market between Member States, European institutions and consumers.

Member States must notify, through the Safety Gate, the corrective measures taken by their surveillance authorities or economic operators in the event of serious risks presented by the product (Article 26.1). A serious risk is defined as "a risk which, based on a risk assessment and taking into account the normal and foreseeable use of the product, is considered to require rapid intervention by the market surveillance authorities, including cases where the effects of the risk are not immediate" (Article 3.5). Within the meaning of Article 19 of the Regulation on Market Surveillance, products presenting a serious risk must, out of principle, be subject to a withdrawal or a recall.

However, if a product does not present a serious risk, Member States only have to notify it through the Safety Gate if they deem this necessary with regard to the urgency of the risk to the health or safety of consumers (Article 26.2).

Member States must also directly notify the European Commission of any risk that was notified through the Safety Gate. The Commission assesses the compliance of the notification and sends it to the other Member States.

In a Delegated Regulation of 27 August 2024 (EU) 2024/3173, the Commission detailed the information that must be included in the notifications of the Member States. These guidelines apply to all notifications, whether or not the risk is serious. All notifications must include:

- Information on the safety requirements applicable to the product;
- An objective description of the risk;
- Information on the corrective measures that were taken or are envisaged;
- Information on the products;
- Traceability information;
- Information provided by economic operators and/or marketplaces through the Safety Business Gateway;
- Any confidentiality request concerning the information. Out of principle, the information provided by economic operators and/or marketplaces will be made available to the public, but they can ask that the information remain confidential, to the extent necessary to ensure that clear and accurate information is

provided to consumers (Article 33). Nevertheless, if the information is covered by professional secrecy, it must be protected in accordance with EU and national applicable law.

The notification of a serious risk must be submitted without delay and in any case within four working days after the implementation of corrective measures.

Furthermore, the European Commission, in the same Delegated Regulation mentioned above, specifies the assessment criteria of the risk presented by the product. In particular, the Commission establishes an assessment table of the severity of the risk on scale of one to four, four being the highest severity level:

Member States shall apply the classification set out in this table when assessing the level of the risk of a product.

	Severity description	
Harm level	Health/safety harm	Other harm
4	Life-threatening: harm or consequence that is or could be fatal, including brain death; consequences that affect reproduction or offspring; severe loss of limbs and/or function, leading to more than approximately 10 % of disability.	Large negative effect, irreversible in several aspects, whether or not acute.
3	Severe: harm or consequence that normally requires hospitalisation and will affect functioning for more than 6 months or lead to a permanent loss of function.	Significant negative effect, significant effort to reverse by specialist intervention, irreversible without this intervention and effort.
2	Moderate: harm or consequence for which a visit to the hospital may be necessary, but in general, hospitalisation is not required. Functioning may be affected for a limited period, not more than 6 months, and recovery is more or less complete.	Negative effect, reversible within a certain period, specialist intervention is required.
1	Minor: harm or consequence that after basic treatment (first aid, normally not by a doctor) does not substantially hamper functioning or cause excessive pain; usually the consequences are completely reversible.	Negative effect, usually completely reversible within the short term without specialist intervention.

It has also established an assessment table relating to the probability of harm:

3.4.4. Member States shall apply the probability index set out in the table.

Probability of occurrence of the harm scenario during the foreseeable lifetime of the product	
Higher or equal to 50 %	Very frequent
Between 5/10 and 1/10	Frequent
Between 1/10 and 1/100	Common
Between 1/100 and 1/1 000	Occasional
Between 1/1 000 and 1/10 000	Unlikely
Between 1/10 000 and 1/100 000	Unusual
Between 1/100 000 and 1/1 000 000	Rare
Lower or equal to 1/1 000 000	Extremely rare

Lastly, it provides a grid to assess the level of risk through the combination of severity and probability of the risk:

Probability of occurrence of the harm during foreseeable lifetime of the product		Severity of harm			
		1	2	3	4
High	> 50 %	H	S	S	S
	> 1/10	M	S	S	S
	> 1/100	M	S	S	S
	> 1/1 000	L	H	S	S
	> 1/10 000	L	M	H	S
	> 1/100 000	L	L	M	H
	> 1/1 000 000	L	L	L	M
Low	< 1/1 000 000	L	L	L	L

S – Serious Risk
H – High risk
M – Medium risk
L – Low risk

However, certain risks should be presumed serious, which is notably the case of risks for which no sufficient precautionary measures exist that could reasonably be implemented by consumers for their protection; the risks defined as serious in the economic operators' and/or marketplaces' notifications through the Safety Business Gateway; the products that were subject to a recall, withdrawal or content removal on a voluntary basis by the economic operators and/or marketplaces; etc.

In addition, the Commission must also decide between divergent assessments of risks between Member States (Article 29.2). Indeed, if a product is considered hazardous in a Member State, it is also presumed to be dangerous in all the other Member States (Article 29.1). Yet, they can challenge the assessment of the risk by another Member State. The Commission must then issue an opinion on the level of risk, without undue delay.

Lastly, for products presenting serious risks, the European Commission can take any appropriate measure by means of implementing acts if the risk cannot be dealt with under other procedures provided for by other more specific texts and can only be efficiently eliminated at EU level (Article 28). These measures include the prohibition, suspension or restriction of the placing on the market authorisation of the concerned product. Furthermore, the Commission can also require, beforehand, when the product is likely to present a serious risk, the implementation of a traceability system to which economic operators must adhere (Article 18).

We understand that this traceability obligation should be imposed by the Commission after reviewing the number of recorded accidents for a specific category of products, as well as the results of the joint activities carried out by the market surveillance authorities pursuant to Article 31. Nevertheless, the implementation of such a traceability system must still be defined.

3.3 Market surveillance by consumers

Within the meaning of Article 34 of the Regulation, the Safety Gate portal used by the Member States offers an interface dedicated to consumers. Access to the Safety Gate is free and enables consumers to be informed about the safety of the products placed on the European market.

The Safety Gate also enables consumers and any interested party to inform the European Commission of products that might present a safety or health risk for consumers. The Commission reviews the accuracy of these notifications and sends them, if applicable, to the concerned Member States, and keeps the author updated on the progress of the action (Article 34.3).

The Commission passed an implementing act detailing the applicable procedure for safety notifications submitted by consumers (Implementing Regulation (EU) 2024/1740 of 21 June 2024). The Safety Gate must enable consumers to enter information on the identification of the product, the distribution chain and notably the responsible economic operator within the meaning of Article 16 of the Regulation or the marketplace that made the product available on the market, the risk of the product, their own identity and residing State, etc.

In addition, the Regulation governs the consumers' rights in the event of a product recall (Article 37). The economic operator responsible for the product recall offers consumers an effective, cost-free and timely remedy. The consumer must be able to choose between two of the following remedies:

- The repair of the recalled product;

- The replacement of the product with a safe product of the same type, with the same value and quality; or

- An adequate refund of the value of the product, provided that the amount of the refund is at least equal to the price paid by the consumer.

However, the remedies offered by the economic operator must not trigger disproportionate costs. Therefore, in such a case, the economic operator can offer the consumer only remedy.

The consumer can still obtain the refund of the product if the economic operator responsible for the recall did not perform the repair or replacement within a reasonable timeframe and without major inconvenience for the consumer (Article 37.2).

The repair performed by the consumer is considered as an effective remedy only if it can be easily and safely performed and if it was contemplated in the recall notice (Article 37.3). In such a case, the operator provides the required instructions to the consumer for the repair the product, as well as all the spare parts or software updates for free.

In any case, the remedy offered to the consumers must not trigger any major inconvenience (Article 37.4).

Lastly, Article 39 of the Regulation provides that consumers can bring representative actions[8] against economic operators and marketplaces in case of a breach of their obligations pursuant to this Regulation.

Regulation (EU) 2023/988 of 10 May 2023 on general product safety is therefore the cornerstone of the protection of the safety and health of consumers on the European market. The revision of Directive 2001/95/EC had become necessary to harmonise the practices of the Member States and to clarify the obligations of economic operators as well as providers of online marketplaces. This notably implied the modernisation of the principles and tools.

Therefore, the Regulation offers a minimum standard of assessment of the safety of products made available on the European market and sets the essential rules in terms of market surveillance. To facilitate the exchange of information and strengthen the efficiency of the protection of consumers, market surveillance is mainly organised around one single interface, the Safety Gate portal, offering different functions depending on the needs of each stakeholder, including economic operators (i.e. the Safety Business Gate), consumers and the Member States / national authorities (i.e. the Safety Gate portal).

[8] See Directive (EU) 2020/1828

Moreover, the obligations of each link of the distribution chain are now well identified and the Regulation designates an operator established in the EU that is necessarily responsible for the obligations related to the safety of products.

Lastly, pursuant to the Regulation, the Commission passed several acts that should facilitate the interpretation and application of the obligations of each stakeholder. However, it ought to be noted that the Regulation, in Article 2.5, provides that the precautionary principle is duly taken into account to implement it. The precautionary principle is a principle that provides that in the absence of certainty as to the risk of a product for the safety of consumers, it is necessary to apply the highest protection measures depending on the global assessment of the risk. For instance, if an economic operator assesses the risk as low to medium, the latter should apply the measures that would be necessary in the event of a medium risk. Therefore, the Regulation seems to invite economic operators and marketplaces to be careful and encourage them to favour the safest corrective measures in the light of certain economic interests that might lead to restricting them.

The Regulation does not provide for the applicable penalties in the event of breaches by economic operators and marketplaces of their obligations. It refers to national laws (Article 44). For instance, in France, the fact for an economic operator not to inform consumers and market surveillance authorities in case of a product presenting a risk, and not to implement the necessary corrective measures to guarantee the conformity of the product is punished, for natural persons, by a prison sentence of 5 years and a fine of €600,000; and a fine of €3,000,000 for legal persons. The amount of the fine can be increased, proportionally to the profit made from the breach, to 10% of the average annual turnover, based on the three last annual turnovers available on the date of the breach[9].

Hence, the Regulation is essential, and it is crucial to quickly take note of it...

[9] See Article L.452-5-1 of the French Consumer Code

ANNEX

Example of a recall notice established by the European Commission and annexed to Implementing Regulation (EU) 2024/1435 of 24 May 2024.

OJ L of 27.05.2024 EN

Annex

[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.

Company logo (optional)

Product Safety Recall

Date

[APOLOGY (OPTIONAL)]

[LINKS TO SOCIAL MEDIA / WEBSITE (OPTIONAL)]

[QR CODE or other technical solution leading to recall page / more information (OPTIONAL)]

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

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

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