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From: General Secretariat of the Council  
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Subject: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council, and repealing Council Directive 87/357/EEC and Directive 2001/95/EC of the European Parliament and of the Council  
- Letter to the Chair of the European Parliament IMCO Committee

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Following the Permanent Representatives Committee meeting of 21. December which endorsed the final compromise text with a view to agreement, delegations are informed that the Presidency sent the attached letter, together with its Annex, to the Chair of the European Parliament IMCO Committee.

SGS 22 / 06014



Council of the  
European Union

Brussels, 21/12/2022

**Mme. Anna CAVAZZINI**

Chair, Committee on the Internal Market and Consumer Protection  
European Parliament  
Rue Wiertz 60, B-1047 Bruxelles  
Belgium

**Subject: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council, and repealing Council Directive 87/357/EEC and Directive 2001/95/EC of the European Parliament and of the Council [2021/0171 (COD)]**

Dear Ms CAVAZZINI,

Following the informal meeting on 28 and 29 November 2022 between the representatives of the three institutions, a draft overall compromise package was agreed today by the Permanent Representatives' Committee.

I am therefore now in a position to confirm that, should the European Parliament adopt this position at the first reading in accordance with Article 294(3) of the Treaty on the Functioning of the European Union (TFEU) in the form as set out in the compromise package contained in the Annex to this letter (subject to revision by the lawyer linguistics of both institutions), the Council would, in accordance with Article 294(4) TFEU, approve the European Parliament's opinion and the act shall be adopted in the wording which corresponds to the European Parliament's position.

On behalf of the Council I also wish to thank you for your close cooperation which should enable us to reach agreement of this dossier at the first reading.

Yours faithfully,

J. ZAJÍČEK  
Chairman of the  
Permanent Representatives Committee

Copy: Mr **Didier REYNDERS**, Member of the European Commission  
Ms **Dita CHARANZOVÁ**, Rapporteur of the IMCO Committee of the European Parliament

2021/0170 (COD)

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Council Directive 87/357/EEC and Directive 2001/95/EC of the European Parliament and of the Council**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee<sup>1</sup>,

Acting in accordance with the ordinary legislative procedure,

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<sup>1</sup> OJ C , , p. .

Whereas:

- (1) Directive 2001/95/EC of the European Parliament and of the Council<sup>2</sup> lays down the requirement that consumer products must be safe and that Member States' market surveillance authorities must take action against dangerous products as well as exchange information to that effect through the “Union rapid information exchange system”, RAPEX.
- (2) Directive 2001/95/EC needs to be revised and updated in light of the developments related to new technologies and online selling, to ensure consistency with developments in the Union harmonisation legislation and in the standardisation legislation, to ensure a better functioning of the product recalls as well as to ensure a clearer framework for food-imitating products so far regulated by Council Directive 87/357/EEC<sup>3</sup>. In the interest of clarity, Directive 2001/95/EC, as well as Directive 87/357/EEC, should be repealed and replaced by this Regulation.
- (3) A Regulation is the appropriate legal instrument as it imposes clear and detailed rules which do not give room for divergent transposition by Member States. The choice of Regulation instead of Directive also allows to better deliver on the objective to ensure coherence with the market surveillance legislative framework for products falling under the scope of Union harmonisation legislation as set out in Regulation (EU) 2019/1020, where the applicable legal instrument is also of the same type, namely Regulation (EU) 2019/1020 of the European Parliament and of the Council<sup>4</sup>. Finally, such a choice will further reduce the regulatory burden through a consistent application of product safety rules across the Union.

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<sup>2</sup> Directive 2001/95/EC of the European Parliament and of the Council on general product safety (OJ L 11, 15.1.2002, p. 4).

<sup>3</sup> Council Directive 87/357/EEC of 25 June on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers (OJ L 192, 11.7. 1987, p. 49).

<sup>4</sup> Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1).

- (4) The aim of this instrument is to contribute to the attainment of the objectives referred to in Article 169 of the Treaty. In particular, it should aim at ensuring health and safety of consumers and the functioning of the internal market as regards products intended for consumers.
- (5) This Regulation should aim at protecting consumers and their safety as one of the fundamental principle of the EU legal framework, enshrined in the EU Charter of fundamental rights. Dangerous products can have very negative consequences on consumers and citizens. All consumers, including the most vulnerable, such as children, older persons or persons with disabilities, have the right to safe products. Consumers should have at their disposal sufficient means to enforce such rights, and Member States adequate instruments and measures at their disposal to enforce this Regulation.
- (6) Despite the development of sector-specific Union harmonisation legislation that addresses safety aspects of specific products or categories of products, it is practically impossible to adopt Union legislation for all consumer products that exist or may be developed. There is therefore **■** a need for a ***broad-based*** legislative framework of a horizontal nature to fill gaps and ***therefore to complement provisions in existing or forthcoming sector-specific Union harmonisation legislation and*** ensure consumer protection not otherwise ensured ***by that legislation***, in particular with a view to achieving a high level of protection of safety and health of consumers, as required by Article 114 and Article 169 of the Treaty.
- (7) At the same time, in respect of products subject to sector-specific Union harmonisation legislation, the scope of application of the different parts of this Regulation should be clearly set out to avoid overlapping provisions and an unclear legal framework.

(8) Whilst some of the provisions such as those concerning most of the obligations of economic operators should not apply to products covered by Union harmonisation legislation since already covered in such legislation, a certain number of other provisions should apply in order to complement Union harmonisation legislation. In particular the general product safety requirement and related provisions should be applicable to consumer products covered by Union harmonisation legislation when certain types of risks are not covered by that legislation. The provisions of this Regulation concerning the obligations of *providers of* online marketplaces, the obligations of economic operators in case of accidents, the right of information *and remedy* for consumers as well as the recalls of consumer products should apply to products covered by Union harmonisation legislation *to the extent that* there are not specific provisions with the same objective in such legislation. Likewise RAPEX is already used for the purposes of Union harmonisation legislation, as referred to in Article 20 of Regulation (EU) 2019/1020 of the European Parliament and of the Council<sup>5</sup>, therefore the provisions regulating the Safety Gate and its functioning contained in this Regulation should be applicable to Union harmonisation legislation.

*(8a) Pursuant to Regulation (EU) 2013/952, products from third countries intended to be made available on the Union market or intended for private use or consumption within the customs territory of the Union are placed under the customs procedure ‘release for free circulation’. This procedure aims at completing the formalities laid down in respect of the import of the goods, including the enforcement of the applicable provisions of Union law, so that these goods can be made available on the Union market like any product made in the Union. As far as consumer safety is concerned, these products are required to comply with this Regulation and, in particular, with the general safety requirement laid down in it.*

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<sup>5</sup> Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1).

- (9) The provisions of Chapter VII of Regulation (EU) 2019/1020, setting up the rules of controls on products entering the Union market, are already directly applicable to products covered by this Regulation. **The** authorities in charge of these controls **should** perform them on the basis of risk analysis as referred to in Articles 46 and 47 of Regulation (EU) No 952/2013 (the Union Customs Code), the implementing legislation and corresponding guidance. This **Regulation therefore** does not modify in any way Chapter VII of Regulation 2019/1020 **and the way** the authorities in charge of controls on products entering the Union market **organise themselves and perform** their activities. ■
- (9a) ***The legal framework for market surveillance of products covered by Union harmonisation legislation and set out in Regulation (EU) 2019/1020 and the legal framework for market surveillance of products covered by this Regulation should be as coherent as possible. It is therefore necessary, as far as market surveillance activities, obligations, powers, measures, and cooperation among market surveillance authorities are concerned, to align the two sets of provisions. For that purpose [Articles 10 to 16, Articles 18 and 19 and Articles 21 to 24] of Regulation (EU) 2019/1020 should be applicable also to products covered by this Regulation.***
- (9b) ***Member States should also ensure that the authorities have sufficient expertise and resources for all their enforcement activities.***
- (10) ■
- (11) ■
- (12) Products which are designed exclusively for professional use but which have subsequently migrated to the consumer market should be subject to this Regulation because they could pose risks to the health and safety of consumers when used under reasonably foreseeable conditions.

- (12a) *Medicinal products are subject to a pre-market assessment that includes a specific risk-benefit analysis. They should therefore be excluded from the scope of this Regulation.*
- (13) Union legislation on food, feed and related areas sets up a specific system ensuring the safety of the products covered by it. *Food and feed products have indeed a specific legal framework established, in particular, by Regulation (EC) 178/2002. Furthermore, food and feed products are regulated by Regulation (EU) 2017/625 ensuring a harmonised approach with regard to official controls for verifying compliance with feed and food law, animal health and animal welfare rules.* Therefore, food and feed should be excluded from the scope of this Regulation with the exception of materials and articles intended to come into contact with food insofar as risks are concerned that are not covered by Regulation (EC) No 1935/2004 of the European Parliament and of the Council<sup>6</sup> or by other food specific legislation which only covers chemical and biological food-related risks.
- (14) █
- (14a) *Living plants have a specific legal framework provided for, in particular, by Regulation (EU) 2016/2031 taking into consideration the specificities to ensure the safety of these products.*
- (14b) *Animal by-products are materials of animal origin that people do not consume. These products, such as feed, are very specific products which have a specific legal framework, in particular Regulation (EC) 1069/2009.*
- (14c) *Plant protection products, also referred as pesticides, have specific provisions for their authorisation at national level, based on Regulation (EC) No 1107/2009, and should therefore be excluded as well from the scope of application of this Regulation.*

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<sup>6</sup> Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).



- (15) Aircraft referred to in Article 2(3) point (d) of Regulation (EU) 2018/1139<sup>7</sup> are subject to the regulatory control of the Member States, in light of their limited risk to civil aviation safety. They should therefore be excluded from the scope of this Regulation.
- (16) The requirements laid down in this Regulation should apply to second hand products or products that are repaired, **reconditioned** or recycled that re-enter the supply chain in the course of a commercial activity, except for those 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 as collectible items of historical significance**.

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<sup>7</sup> Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1–122).

- (17) Directive 87/357/EEC on ■ consumer products which, although not foodstuff, resemble foodstuff and are likely to be confused with foodstuff in a way that consumers, especially children, may place them in their mouths, suck or ingest them and which might cause, for example, suffocation, poisoning, the perforation or obstruction of the digestive tract, has given rise to controversial interpretation. Furthermore it has been adopted at a time where the legal framework for consumer product safety was very limited in scope. For these reasons, Directive 87/357/EEC should be repealed **and replaced by provisions of this Regulation, in particular those ensuring that, following risk assessment, product which can be harmful when placed in mouth, sucked or ingested and which are likely to be confused with foodstuff due to their form, odour, colour, appearance, packaging, labelling, volume, size or other characteristics, should be considered dangerous. In performing their evaluation, market surveillance authorities should take into consideration, among other elements, that as held by the Court of Justice of the European Union, it is not necessary to demonstrate by objective and substantiated data that placing in the mouth, sucking or ingesting food-imitating products may entail risks such as suffocation, poisoning, or the perforation or obstruction of the digestive tract. Nevertheless, the competent national authorities must assess on a case-by-case basis whether such products are dangerous and justify their assessment.**
- (18) Services should not be covered by this Regulation. However, in order to secure the attainment of the protection of health and safety of consumers, products that are supplied or made available to consumers in the context of the provision of services, including products to which consumers are directly exposed during a service provision, should fall within the scope of this Regulation. **However**, equipment on which consumers ride or travel, **when it is directly** operated by a service provider **within the context of a transport service**, should be excluded from the scope of this Regulation since it has to be dealt with in conjunction with the safety of the service provided.

- (18a) *Works of art, collectors' items and antiques are specific categories of products which cannot be expected to meet the safety requirements laid down by the present Regulation, and they should therefore be excluded from its scope. However, in order to prevent other products from being mistakenly considered as belonging to these categories, it should be necessary to take into account that works of art should only be products created solely for artistic purposes, that collector's items should be of sufficient rarity and historical or scientific interest to justify their collection and preservation, and that antiques, if they do not already fall in the first two above-mentioned categories, should be of an out of the ordinary age. When assessing a product as a work of art, collector's item or antique, Annex IX of Directive 2006/112/EC on the common system of value added tax could be taken into account.*
- (18c) *According to the general safety requirement laid down in this Regulation, economic operators are obliged to place only safe products on the market. Such a high level of safety should be primarily achieved by design and the features of the product, taking into account the intended and foreseeable use and conditions of use of the product. The remaining risks, if any, should be alleviated with certain safeguards, such as warnings and instructions.*
- (19) Items which connect to other items or non-embedded items which influence the way another item works can present a risk for the safety of the product. That aspect should be taken into due consideration as a potential risk. The connections and interrelation that an item might have with external items should not jeopardise its safety.
- (20) New technologies *might also pose* new risks to consumers' health and safety or change the way the existing risks could materialise, such as an external intervention hacking the product or changing its characteristics. *New technologies, such as through software updates, may substantially modify the original product, which could then be submitted to a new risk assessment if that substantial modification has an impact on the safety of the product.*

- (21) The World Health Organisation defines ‘health’ as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. ■
- (22) Specific cybersecurity risks affecting the safety of consumers as well as protocols and certifications can be dealt with by sectorial legislation. However, it should be ensured *that, in cases where* the sectorial legislation *does not apply*, the relevant economic operators and national authorities take into consideration risks linked to new technologies, respectively when designing the products and assessing them, in order to ensure that changes introduced in the product do not jeopardise its safety.
- (23) The safety of products should be assessed taking into account all the relevant aspects, notably their characteristics, *such as physical, mechanical and chemical characteristics*, and presentation as well as the specific needs and risks, *which may also include environmental risk inasmuch as it poses a risk to the health and safety of consumers*, for categories of consumers who are likely to use the products, in particular children, older persons and persons with disabilities. *That assessment should take into account the health risk posed by digital connected products, including on mental health, especially on vulnerable consumers, in particular children.* Therefore, *when assessing the safety of digital connected products likely to have an impact on children, manufacturers should ensure that the products they make available on the market meet the highest standards of safety, security and privacy by design in the best interests of children.* Furthermore, if specific information is necessary to make products safe toward a given category of persons, the assessment of the safety of the products should take into consideration also the presence of this information and its accessibility. The safety of *all* products should be assessed taking into consideration the need for the product to be safe over its entire lifespan.

- (24) Economic operators should have *proportionate* obligations concerning the safety of products, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of the health and safety of consumers, *while also ensuring efficient functioning of the internal market*. All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market products, which are safe and in conformity with this Regulation. It is necessary to provide for a clear and proportionate distribution of obligations corresponding to the role of each operator in the supply and distribution process. *For example, when it comes to the verification of whether the manufacturer and, where relevant, importer complied with their obligations, distributors should only be required to perform factual verifications and not an assessment of the information provided by them. The information about the identification of the product, of the economic operators and instructions and safety information could be additionally provided by the economic operators in a digital form by means of electronic solutions, such as a QR or data matrix code.*
- (24b) *In order for economic operators that are SMEs and micro-businesses to be able to cope with the new obligations imposed by this Regulation, the Commission should provide practical guidelines and tailored guidance, for example, a direct channel to connect to experts in case of questions, taking into account the need to simplify and limit their administrative burdens.*

*(24c) In order to prevent the placing on the market of dangerous products, it should be compulsory for economic operators to introduce into their production or marketing activities internal processes ensuring compliance with the relevant requirements of this Regulation. Such processes – which can be based, for example, upon organisational procedures, guidelines, standards or ad hoc manager – 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 under the sole responsibility of relevant economic operators while their objective being to allow economic operators to comply with relevant requirements provided for them by this Regulation.*

*(24d) Cooperation from all economic operators and providers of online marketplaces with market surveillance authorities in order to eliminate or mitigate risks for the relevant products made available on the market is essential. However, the requests made to them by market surveillance authorities should be tailored to the role they play in the supply chain and with regards to their respective legal obligations.*

(25) Distance selling, including online selling, should also fall within the scope of this Regulation. Online selling has grown consistently and steadily, creating new business models, *new challenges regarding product safety* and new actors in the market such as the *providers of* online marketplaces.

- (25b) *In the case of a product offered for sale online or through other means of distance sales, the product should be considered to have been made available on the market if the offer for sale is targeted at consumers in the Union. In line with the applicable Union rules on private international law, a case-by-case analysis should be carried out in order to establish whether an offer is targeted at consumers in the Union. An offer for sale should be considered to be targeted at consumers in the Union if the relevant economic operator directs, by any means, its activities to a Member State. For the case-by-case analyses, relevant factors, such as the geographical areas to which dispatch is possible, the languages available, used for the offer or for ordering, means of payment, the use of currency of the Member State or a domain name registered in one of the Member States need to be taken into consideration. In the case of online sales, the mere fact that the economic operators' or the providers of online marketplaces' interface is accessible in the Member State in which the consumer is established or domiciled is insufficient.*
- (26) *Providers of* online marketplaces play a crucial role in the supply chain - allowing economic operators to reach an indefinite number of consumers - and therefore also in the product safety system.

*(26a) Under the new complex business models linked to online sales, the same entity can provide a variety of services. Depending on the nature of the services provided for a given product, the same entity may fall within different categories of business models under this Regulation. When an entity provides only online intermediation services for a given product, then it qualifies only as a provider of an online marketplace for this product. In case the same entity provides both online marketplace services for the sale of a particular product and also acts as an economic operator in this Regulation, it would qualify also as the relevant economic operator. In such a case, the entity in question would therefore have to comply with those obligations prescribed for the given economic operator in question. For instance, if the provider of the online marketplace also distributes a product, then, with respect to the sale of the distributed product, it would be considered to be a distributor. Similarly, if the entity in question sells its own branded products, it would act as a manufacturer and would thus need to comply with the applicable requirements for manufacturers. Also some entities can qualify as fulfilment service providers if they offer fulfilment services. Such cases would thus need to be assessed on a case-by-case basis.*



(27) Given the important role played by *providers of* online marketplaces when intermediating the sale of products between traders and consumers, such actors should have more responsibilities in tackling the sale of dangerous products online. Directive 2000/31/EC of the European Parliament and of the Council<sup>8</sup> provides the general framework for e-commerce and lays down certain obligations for online platforms. Regulation [.../...] on a Single Market for Digital Services (Digital Services Act) and amending Directive 2000/31/EC<sup>9</sup> regulates the responsibility and accountability of providers of intermediary services online with regard to illegal contents, including *dangerous* products. That Regulation applies without prejudice to the rules laid down by Union law on consumer protection and product safety. Accordingly, building on the horizontal legal framework provided by that Regulation, specific requirements essential to effectively tackle the sale of dangerous products online should be introduced, in line with Article 2(4), point (f) of that Regulation. *To the extent that this Regulation specifies the requirements, in relation to product safety, with which providers of online marketplaces must comply in order to ensure compliance with certain provisions of Regulation (EU) 2022/2065 [the DSA], those requirements should not affect the application of Regulation 2022/2065, which continues to apply to those providers.*

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<sup>8</sup> Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') - OJ L 178, 17.7.2000, p. 1–16.

<sup>9</sup> Regulation [.../...] on a Single Market for Digital Services (Digital Services Act) and amending Directive 2000/31/EC.

- (28) The Product Safety Pledge, signed in 2018 and joined by a number of marketplaces since then, provides for a number of voluntary commitments on product safety. The Product Safety Pledge has proved its rationale in enhancing the protection of consumers against dangerous products sold online. *In order to strengthen the protection of consumers by avoiding damage to their life, health and safety and to ensure fair competition in the internal market, providers of online marketplaces are encouraged to take those voluntary commitments to prevent the re-appearance of listings of dangerous products already withdrawn. The use of technologies and digital processes and the improvements in alert systems, in particular Safety Gate, can allow the automatic identification and communication of notified dangerous products and to carry out automated random checks against the Safety Gate.*
- (28a) *This Regulation should also lay down provisions encouraging economic operators and providers of online marketplaces to enter into voluntary memoranda of understanding with competent authorities, the Commission or organisations representing consumers or economic operators to undertake product safety related voluntary commitments that go beyond the legal obligations laid down in Union law.*
- (29) *Providers of* online marketplaces should act with due care in relation to the content hosted on their online interfaces that concerns safety of products, in accordance with the specific obligations laid down in this Regulation. Accordingly, due diligence obligations for all *providers of* online marketplaces should be established in relation to the content hosted on their online interfaces that concerns safety of products.

- (30) Moreover, for the purposes of effective market surveillance, *providers of* online marketplaces should register in the Safety Gate portal and indicate, in the same portal, the information concerning their single contact points for the facilitation of communication of information on product safety issues. The *Commission should ensure that the registration is easy and user-friendly. The* single point of contact under this Regulation might be the same as the point of contact under Article *11* of Regulation (EU) .../...[the Digital Services Act], without endangering the objective of treating issues linked to product safety in a swift and specific manner.
- (30a) *The providers of online marketplaces should designate a single point of contact for consumers to serve as a single window for consumer communications on product safety issues, which may then be redirected to the proper service unit of an online marketplace. This should not prevent additional points of contact for specific services being made available to consumers. The single point of contact under this Regulation might be the same as the point of contact under Article 12 of Regulation (EU) .../...[the Digital Services Act].*
- (31) In order to be able to comply with their obligations under this Regulation, in particular in respect of timely and effective compliance with the orders of public authorities, processing of notices of other third parties and cooperating with market surveillance authorities in the context of corrective measures upon request, *providers of* online marketplaces should have in place an internal mechanism for handling product safety-related issues.

- (32) The obligations imposed by this Regulation on **providers of** online marketplaces should neither amount to a general obligation to monitor the information which they transmit or store, nor to actively seek facts or circumstances indicating illegal activity, such as the sale of dangerous products online. **Providers of** online marketplaces should, nonetheless, expeditiously remove content referring to **an offer of** dangerous products from their online interfaces, upon obtaining actual knowledge or, in the case of claims for damages, awareness of the **content referring to an offer of dangerous products**, in particular in cases where the **provider of** online marketplace has been made aware of facts or circumstances on the basis of which a diligent economic operator should have identified the illegality in question, in order to benefit from the exemption from liability for hosting services under the 'Directive on electronic commerce' and the [Digital Services Act]. Online marketplaces should process notices concerning content referring to **an offer of dangerous** products, received in accordance with [Article 14] of Regulation (EU) .../...[the Digital Services Act], within the additional timeframes established by this Regulation. **In addition, providers of online marketplaces are encouraged to check products with Safety Gate Portal before placing them on their interface.**
- (33) Article 14(4) of Regulation (EU) 2019/1020 provides market surveillance authorities with the power, where no other effective means are available to eliminate a serious risk, to require the removal of content referring to the related products from an online interface or to require the explicit display of a warning to end users when they access an online interface. The powers entrusted to market surveillance authorities by Article 14(4) of Regulation (EU) 2019/1020 should also apply to this Regulation. For effective market surveillance under this Regulation and to avoid dangerous products being present on the Union market, this power should apply in all necessary and proportionate cases and also for products presenting a less than serious risk. It is essential that **providers of** online marketplaces comply with such orders as a matter of urgency. Therefore, this Regulation introduces binding time limits in this respect. This power should be exercised in accordance with Article 9 of the Digital Services Act.

- (33a) *Orders which also require the provider of an online marketplace to remove from its online interface all identical content referring to the offer of a dangerous product specified in the order, should identify the elements that will determine and allow the provider of online marketplace to remove identical offers, based on the information displayed by the traders, to the extent that it does not require the provider of online marketplace to carry out an independent assessment of that content.*
- (34) **█** Where the information from the Safety Gate *Rapid Alert System* does not contain an exact uniform resource locator (URL) and, where necessary, additional information enabling the identification of the **█** content *referring to an offer of dangerous products, providers of* online marketplaces should nevertheless take into account the transmitted information, such as product identifiers, when available, and other traceability information, in the context of any measures adopted by *providers of* online marketplaces on their own initiative aiming at detecting, identifying, removing or disabling access to *such offers of* dangerous products **█** on their marketplace, where applicable. *Nonetheless, the Safety Gate Portal should be modernised and updated in order to make it easier for providers of online marketplaces to detect unsafe products and, with that aim, it should be possible to implement the provisions on the removal of content referring to an offer of dangerous products from online interfaces by means of a notification system designed and developed within the Safety Gate.*
- (35) For the purposes of Article 22 of Regulation (EU) .../...[the Digital Services Act], and concerning the safety of products sold online, the Digital Services Coordinator should consider in particular consumer organisations and associations representing consumers' interest *and other relevant stakeholders*, upon their request, as trusted flaggers, provided that the conditions set out in that article have been met.

- (36) Product traceability is fundamental for effective market surveillance of dangerous products and corrective measures. Consumers should also be protected against dangerous products in the same way in the offline and online sales channels, including when purchasing products on online marketplaces. Building on the provisions of Regulation (EU) .../...[the Digital Services Act]concerning the traceability of traders, **providers of** online marketplaces should not allow **a specific product offer being listed** on their platforms unless the trader provided all information related to product safety and traceability as detailed in this Regulation. Such information should be displayed together with the product listing so that consumers can benefit from the same information made available online and offline. However, the **providers of an** online marketplace should not be responsible for verifying the completeness, correctness and the accuracy of the information itself, as the obligation to ensure the traceability of products remains with the **relevant** trader.
- (37) It is also important that **providers of** online marketplaces closely cooperate with the market surveillance authorities, **with traders** and with relevant economic operators on the safety of products. An obligation of cooperation with market surveillance authorities is imposed on information society service providers under Article 7(2) of Regulation (EU) 2019/1020 in relation to products covered by that Regulation and should therefore be extended to all consumer products. For instance, market surveillance authorities are constantly improving the technological tools they use for the online market surveillance to identify dangerous products sold online. For these tools to be operational, **providers of** online marketplaces should grant access to their interfaces. Moreover, for the purpose of product safety, market surveillance authorities may also need to scrape data from **an online interface upon reasoned request in case of technical obstacles put in place by providers of** online marketplaces **or online sellers. Providers of online marketplaces should also cooperate on product recalls and on accident reporting.**

- (38) Direct selling by economic operators established outside the Union through online channels hinders the work of market surveillance authorities when tackling dangerous products in the Union, as in many instances economic operators may not be established nor have a legal representative in the Union. It is therefore necessary to ensure that market surveillance authorities have adequate powers and means to effectively tackle the sale of dangerous products online. In order to ensure an effective enforcement of this Regulation, the obligation set out in Article 4(1), (2) and (3) of Regulation 2019/1020 should be extended also to products falling outside the scope of the Union harmonisation legislation to ensure that there is a responsible economic operator established in the Union, which is entrusted with tasks regarding such products, providing market surveillance authorities with an interlocutor and, *where appropriate with regard to the possible risks related to a product, performing specific tasks in a timely manner to ensure that the products are safe. Those specific tasks should include regular checks with regard to the compliance with the technical documentation, product and manufacturer information, instruction and safety information.*
- (39) Contact information of the economic operator, established in the Union and responsible for products falling under the scope of application of this Regulation should be indicated with the product in order to facilitate checks throughout the supply chain.
- (40) █
- (41) Any *natural or legal person* that either places a product on the market under their own name or trademark or *substantially* modifies a product in such a way that conformity with the requirements of this Regulation may be affected, should be considered to be the manufacturer and should assume the obligations of the manufacturer.

- (41a) *Modification, by physical or digital means, to a product might have consequences on the nature and characteristics of the product in a way, which was not foreseen in the initial risk assessment of the product and may jeopardize the safety of the product. It should therefore be considered as a substantial modification and, when not done by the consumer or on his behalf, it should lead to consider that it is a new product from a different manufacturer. In order to ensure the compliance with the general safety requirement, the person that carries out the substantial modification should be considered as the manufacturer and subject to the same obligations. That requirement should only apply with respect to the modified part of the product, provided that the modification does not affect the product as a whole. In order to avoid an unnecessary and disproportionate burden, the person carrying out the substantial modification should not be required to repeat tests and produce new documentation in relation to aspects of the product that are not impacted by the modification. It should be up to the person who carries out the substantial modification to demonstrate that the modification does not have an impact on the product as a whole.*
- (42) Internal conformity procedures through which economic operators ensure, internally, the effective and swift performance of their obligation as well as the conditions to react timely in case of a dangerous product, should be put in place by the economic operators themselves.
- (43) █



(44) Ensuring product identification<sup>10</sup> *and information on the manufacturer and other relevant economic operators* throughout the entire supply chain helps to identify economic operators and, *where applicable*, to take effective *and proportionate* corrective measures against dangerous products, such as targeted recalls. Product identification and *information on the manufacturer and other relevant economic operators* thus ensures that consumers, *including persons with disabilities, and market surveillance authorities* obtain accurate information regarding dangerous products which enhances confidence in the market and avoids unnecessary disruption of trade. Products should therefore bear information allowing their identification and the identification of the manufacturer and, *as applicable*, of the importer *and other relevant economic operators*. Such requirements could be made stricter for certain kinds of products, *susceptible to bear a serious risk to health and safety of consumers, by a system of collection and storage of data enabling, besides the identification of the product, the identification of its components or of the economic operators involved in its supply chain. This should be without prejudice to the information requirements laid down by Directive 2011/83/EU<sup>1a</sup> of the European Parliament and of the Council, such as on the main characteristics of the goods, to the extent appropriate to the medium and to the goods. A picture should be considered as a photograph, illustration or other pictographic element, which easily allows the identification of a product or potential product.*

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<sup>10</sup> *Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council (OJ L 304, 22.11.2011, p. 64).*


(44a) *Manufacturers should draw up technical documentations regarding the products they place on the market, which should contain the necessary information to prove that these products are safe. The technical documentation should be based on an internal risk analysis carried out by the manufacturer. The amount of information to be provided in the technical documentation should be proportionate to the complexity of the product and possible risks identified by the manufacturer. In particular, manufacturers should provide a general description of the product and the elements necessary to assess its safety. In the case of complex products or products presenting possible risks, the information to be provided might need a more extensive description of the product. In such cases, also an analysis of those risks and the technical means adopted to mitigate or eliminate the risks should be included. In case the product complies with European standards or other elements applied to meet the general safety requirement, the list of the relevant European standards or the other elements should also be indicated.*

(45) █

(46) To preserve the coherence of the market surveillance legal framework and, at the same time, ensure an effective cooperation between the European network of the Member States' authorities competent for product safety ('Consumer Safety Network') provided for by this Regulation and the Union Product Compliance Network aimed at structured coordination and cooperation between Member States' enforcement authorities and the Commission provided for by Regulation (EU) 2019/1020, it is necessary to associate the Consumer Safety Network to the Union Product Compliance Network in the activities referred to in Articles 11, 12, 13 and 21 of Regulation (EU) 2019/1020.

(46a) *Member States should ensure that any measure taken by their competent authorities under this Regulation are subject to effective judicial remedies in accordance with Article 47 of the Charter of Fundamental Rights of the European Union.*

- (47) National authorities should be enabled to complement the traditional market surveillance activities focused on safety of products with market surveillance activities focusing on the internal conformity procedures set up by economic operators to ensure product safety. Market surveillance authorities should be able to require the manufacturer to indicate which other products - produced with the same procedure, or containing the same components considered to present a risk or that are part of the same production batch - are affected by the same risk.
- (48) An exchange of information between Member States and the Commission concerning the *application* of this Regulation should be established on the basis of output indicators which would allow measuring *the* effectiveness *of* Union product safety legislation.
- (49) There should be effective, speedy and accurate exchange of information concerning dangerous products *to ensure that appropriate measures are taken in relation to those products and to protect consumers safety.*

- (50) The Union rapid information system (RAPEX) *should be modernised to enable more efficient* corrective measures to be taken across the Union in relation to products that present a risk beyond the territory of a single Member State. It is opportune, though, to change the used abbreviated name from RAPEX to Safety Gate for greater clarity and better outreach to consumers. Safety Gate comprises *three elements: first*, a rapid alert system on dangerous non-food products whereby national authorities and the Commission can exchange information on such products (*Safety Gate Rapid Alert System*), *second*, a web portal to inform the public *and enable them to submit complaints* (Safety Gate portal) and *third* an interface to enable businesses to comply with their obligation to inform authorities and consumers of dangerous products *and accidents* (Safety Business Gateway).
- Interfaces must exist between the different Safety Gate elements. The Safety Gate Rapid Alert System is the internal system through which authorities and the Commission exchange information on measures concerning dangerous products, and it may contain confidential information. An extract of alerts should be published on the Safety Gate portal in order to inform the public about dangerous products. The Safety Business Gateway is the web portal through which businesses inform market surveillance authorities of the Member States about dangerous products and about accidents. The Commission should develop a technical solution to ensure that the information encoded by businesses in the Safety Business Gateway that is meant to alert consumers can be made available to consumers on the Safety Gate Portal without undue delay. In addition, the Commission should develop an interoperable interface to enable providers of online marketplaces to link their interfaces with the Safety Gate Portal in an easy, quick and reliable way.*
- (51) Member States should notify in the Safety Gate *Rapid Alert System* both compulsory and voluntary corrective measures that prevent, restrict or impose specific conditions on the possible marketing of a product because of a serious risk to the health and safety of consumers or, in case of products covered by Regulation (EU) No 2019/1020, also to other relevant public interests of  end-users.

- (52) Under Article 34 of Regulation (EU) 2019/1020, Member States authorities are to notify measures adopted against products covered by that Regulation, presenting a less than serious risk, through the information and communication system referred to in the same article, while corrective measures adopted against products covered by this Regulation presenting a less than serious risk *could also* be notified in the Safety Gate **Rapid Alert System**. Member States and the Commission should make available to the public information relating to *serious* risks to the health and safety of consumers posed by products. It is opportune for consumers and businesses that all information on corrective measures adopted against products posing a *serious* risk are contained in the Safety Gate **Rapid Alert System**, allowing relevant information on dangerous products to be made available to the public through the Safety Gate portal. *It is important to ensure that all of that information is available in the official language(s) of the consumer's Member State of residence and that it is written in clear and understandable language*. Member States are therefore encouraged to notify in the Safety Gate all corrective measures on products posing a risk to the health and safety of consumers.
- (53) In case the information has to be notified in the information and communication system according to Regulation (EU) 2019/1020, there is the possibility, for such notifications, to be submitted directly in the Safety Gate **Rapid Alert System** or, to be generated from within the information and communication system for market surveillance provided for in Article 34 of Regulation (EU) 2019/1020. For this purpose, the Commission should maintain and further develop the interface that has been set up for the transfer of information between the information and communication system and the Safety Gate **Rapid Alert System**, in order to avoid double data entry and facilitate such transfer.

- (54) The Commission should maintain and further develop the Safety Business Gateway web portal, enabling economic operators to comply with their obligations to inform market surveillance authorities and consumers of dangerous products they have made available on the market. ■ It should enable quick and efficient information exchange between economic operators and national authorities, and facilitate information to consumers from economic operators.
- (54a) *Ensuring that manufacturers notify accidents that are caused by a product they made available on the market will improve the information available to market surveillance authorities and allow for a better identification of potentially dangerous categories of products. Rules on product liability of economic operators for defective products are laid down in specific Union legislation and such notification and collection of data should not therefore be considered as an admission of liability for a defective product nor as confirmation of liability under the relevant Union or national legislation.*
- (54b) *In order to be able to detect early emerging new risks and other product safety related market trends, all interested parties, including consumer or business organisations, should be encouraged to signal to market surveillance authorities and to the Commission information available to them to detect and investigate infringements of this Regulation.*
- (55) There might be cases where it is necessary to deal with a serious risk at the Union level where the risk cannot be contained satisfactorily by means of measures taken by the Member State concerned or by any other procedure under Union legislation. This could notably be the case of new emerging risks or those impacting vulnerable consumers. For that reason the Commission can adopt measures either on its own initiative or upon request of the Member States. Such measures should be adapted to the gravity and urgency of the situation. It is furthermore necessary to provide for an adequate mechanism whereby the Commission could adopt immediately applicable interim measures.

- (56) The determination of the risk concerning a product and its level is based on a risk assessment performed by the relevant actors. Member States, in performing risk assessment, might reach different results as far as the presence of a risk or its level is concerned. This could jeopardise the correct functioning of the single market and the level playing field for both consumers and economic operators. A **■** mechanism should therefore be *established to* allow the Commission **■** to provide an opinion on the issue in dispute.
- (56a) *The Commission should draw up a periodic report on the application of the mechanism under Article 27, which should be presented to the Consumer Safety Network. That report should identify the main criteria applied by the Member States for risk assessment and their impact on the internal market and on an equal level of consumer protection, with the aim of enabling Member States and the Commission to harmonise the approaches and criteria for risk assessment.*
- (57) The Consumer Safety Network enhances the cooperation on product safety enforcement between Member States. In particular, it facilitates the activities of exchange of information, the organisation of joint market surveillance activities, the exchange of expertise and best practices. *It should also contribute to harmonisation of the methodologies to collect data on product safety, as well as to an increase in the interoperability between regional, sectorial, national and European information systems for product safety.* The Consumer Safety Network should be duly represented and participate in the coordination and cooperation activities of the Union Product Compliance Network provided for in Regulation (EU) 2019/1020 whenever coordination of activities falling under the scope of application of both Regulations is necessary to ensure their effectiveness.

- (58) Market surveillance authorities *should* carry out joint activities with other authorities or organisations representing economic operators or *consumers*, with a view to promoting safety of products and identifying dangerous products, including those that are offered for sale online. In doing so the market surveillance authorities and the Commission, as appropriate, should ensure that the choice of products and producers as well as the activities performed does not create *situations*, which might distort competition or affect the objectivity, independence and impartiality of the parties. *The market surveillance authorities should make available to the public the agreements on joint activities as soon as possible, providing such publication does not jeopardise the effectiveness of the activities to be undertaken.*
- (58a) *The Commission should organise on regular basis a joint activity whereby market surveillance authorities should conduct inspections on products acquired under a cover identity online or offline, in particular on those products that are most frequently notified within the Safety Gate.*
- (59) Simultaneous coordinated control actions (‘sweeps’) are specific enforcement actions that *could* further enhance product safety *and therefore should be conducted to detect online and offline infringements to this Regulation.* In particular, sweeps should be conducted where market trends, consumer complaints or other indications suggest that certain *products or* product categories are often found to present a serious risk.
- (60) The public interface of the Safety Gate *Rapid Alert System*, the Safety Gate portal, allows the general public, including consumers, economic operators and *providers of* online marketplaces, to be informed about corrective measures taken against dangerous products present on the Union market. A separate section of the Safety Gate portal enables consumers to inform the Commission of products presenting a risk to consumer health and safety found in the market. Where relevant, the Commission should provide adequate follow-up, notably by transmitting such information to the concerned national authorities. *The database and website of the Safety Gate should be easily accessible for persons with disabilities.*



- (60a) *After verification of accuracy of information received from consumers and other interested parties, the Commission should ensure an appropriate follow up. In particular, it should forward the information to the relevant Member States so that the competent market surveillance authority can proceed as appropriate and needed. It is important that consumers and other interested parties are properly informed of the Commission action.*
- (61) *Public access to the information available to the authorities on product safety should, as a general rule, be ensured. However, in making available information on product safety to the public, professional secrecy, as referred to in Article 339 of the Treaty, should be protected in a way which is compatible with the need to ensure the effectiveness of market surveillance activities and of protection measures.*
- (61a) *Complaints are important to raise awareness on national authorities about safety and effectiveness of surveillance and control activities on dangerous products. Member States should therefore give to consumers and other interested parties such as consumer associations and economic operators the possibility to submit complaints in this respect.*

(62) When a product already sold to consumers turns out to be dangerous, it may need to be recalled to protect consumers in the Union. Consumers might not be aware that they own a recalled product. In order to increase recall effectiveness, it is therefore important to better reach consumers concerned. Direct contact is the most effective method to increase consumers' awareness of recalls and encourage action. It is also the preferred communication channel across all groups of consumers. In order to ensure the safety of the consumers, it is important that they are informed in a quick and reliable way. Economic operators *and, where applicable, providers of online marketplaces* should therefore use the customer data at their disposal to inform consumers of recalls and safety warnings linked to products they have purchased. Therefore, a legal obligation is needed to require economic operators *and providers of online marketplaces* to use any customer data already at their disposal to inform consumers of recalls and safety warnings. In this respect, economic operators *and providers of online marketplaces* will make sure to include the possibility to directly contact customers in the case of a recall or safety warning affecting them in existing customer loyalty programmes and product registration systems, through which customers are asked, after having purchased a product, to communicate to the manufacturer on a voluntary basis some information such as their name, contact information, the product model or serial number. *The mere fact that recalls are targeted to consumers should not 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. Economic operators and providers of online marketplaces should be encouraged to take such actions, especially in the case of micro- and small enterprises acting like consumers.*

- (62a) Consumers should be encouraged to register products in order to receive information about recalls and safety warnings. The Commission should be empowered to adopt implementing acts in order to specify that for some specific products or categories of products, consumers should always have the possibility to register a product they have purchased in order to be directly notified about a recall or a safety warning related to this product. In determining the specific products or categories or products subject to this requirement, due consideration should be given to the lifecycle of the products or categories of products at stake, as well as to the risks the products pose, the frequency of recalls and the category of users of the products, in particular vulnerable consumers.*
- (63) A third of consumers continue using dangerous products despite seeing a recall notice, notably because recall notices are drafted in a complex way or minimise the risk at stake. The recall notice should therefore be clear, transparent and clearly describe the risk at stake, avoiding any terms, expressions or other elements that may decrease consumers' perception of risk. Consumers should also be able to get more information, if needed, via a toll-free telephone number or other interactive instrument.

(64) To encourage consumer response to recalls it is also important that the action required from consumers be as simple as possible and that the remedies offered be effective, cost-free and timely. Directive (EU) 2019/771 of the European Parliament and of the Council<sup>11</sup> provides the consumers with the contractual remedies for a lack of conformity of *physical* goods that existed at the time of delivery and became apparent within the liability period *laid down by the Member States in accordance with Article 10(3) of that Directive. Article 14 of Directive (EU) 2019/770 of the European Parliament and of the Council also applies in terms of the tangible medium, such as DVDs, CDs, USB sticks and memory cards, used to carry a digital content. However, situations where dangerous products are recalled from the market justify having a specific set of rules that should be applied without prejudice to contractual remedies because their objectives are different. Whereas contractual remedies serve the purpose to remedy the lack of conformity of the goods with the contract, the remedies in case of a recall serve both to ensure elimination of dangerous products from the market and an adequate remedy for the consumer. As a consequence, there are major differences between the two sets of potential remedies: firstly, in case of a product recall according to this Regulation, there should be no time limitation to activate the remedies; secondly, the consumer should be entitled to ask remedies from the relevant economic operator, not necessarily from the trader. Moreover, in case of a recall, the consumer does not have to prove the product to be dangerous.*

(64a) *Given the different objectives of remedies provided in case of a recall of a dangerous product and remedies for non-conformity of goods with the contract, consumers should use the system corresponding to the relevant situation. For example, if the consumer receives a recall notice with description of the remedies available to the consumer, the consumer should act according to the instructions in the recall notice. Nevertheless, he or she should not be deprived of the possibility to ask for remedies from the seller based on non-conformity of the dangerous goods with the contract.*

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<sup>11</sup> Directive (EU) 2019/771 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the sale of goods, amending Regulation (EU) 2017/2394 and Directive 2009/22/EC, and repealing Directive 1999/44/EC (OJ L 136, 22. 5. 2019, p. 28).

- (64c) Once the consumer was remedied as a follow up of a recall, the consumer could not be entitled to a remedy for non-conformity of the good with the contract for reasons connected with the fact that the product was dangerous because the non-conformity does not exist anymore. Similarly, in case the consumer invokes its rights to remedy under Directive (EU) 2019/771 or Directive (EU) 2019/770, the consumer is not entitled to a remedy under this Regulation for the same safety issue. However, if other requirements for conformity regarding the same good are not fulfilled, the seller would remain liable for such non-conformity of the good with the contract even if there has been a remedy provided to the consumer following a recall of a dangerous product.*
- (64d) Economic operators initiating a product recall should offer consumers at least two options between repair, replacement, or adequate refund of the value of the recalled product, except where impossible or disproportionate. Offering consumers a choice between remedies can improve the effectiveness of a recall. In addition, incentives to motivate consumers to participate in a recall, such as discounts or vouchers, should be encouraged in order to increase the effectiveness of recalls. The repair of the product should only be considered a possible remedy if the safety of the repaired product can be ensured. The amount of the refund should be at least equal to the price paid by the consumer, without prejudice to a further compensation as provided for in national laws. Where no proof of the price paid is available, an adequate refund of the value of the recalled product should still be provided. In case of recalls of the tangible medium of digital products in the meaning of Article 2(1) of Directive (EU) 2019/770, the refund should cover all sums paid by the consumer under the contract, as provided for by Article 16(1) of that Directive. Any remedy should be without prejudice to the consumers' right to damages according to national laws.*

- (64e) Remedies offered in case of a product safety recall should not place an excessive burden on consumers nor place them at risk. If the remedy also entails the disposal of the recalled product, such disposal should be carried out with due consideration of the environmental and sustainable objectives set at Union and national levels. In addition, repair by consumers should only be considered as a possible remedy if it can be carried out easily and safely by the consumer, for instance through the replacement of a battery or by cutting excessively long drawstrings on a children's garment when provided for in the recall notice. Moreover, the repair by the consumer should be without prejudice to consumers rights under Directive (EU) 2019/771 and Directive (EU) 2019/770. Therefore, in such situations, economic operators should not oblige consumers to repair a dangerous product.*
- (64f) Consumers should be entitled to enforce their rights in relation to the obligations imposed on economic operators or providers of online marketplaces under this Regulation through representative actions in accordance with Directive (EU) 2020/1828 of the European Parliament and of the Council. For that purpose, this Regulation should provide that Directive (EU) 2020/1828 is applicable to the representative actions concerning infringements of the provisions of this Regulation that harm or can harm the collective interests of consumers. The Annex to that Directive should therefore be amended accordingly. It is for the Member States to ensure that that amendment is reflected in their transposition measures adopted in accordance with Directive (EU) 2020/1828, although the adoption of national transposition measures in this regard is not a condition for the applicability of that Directive to those representative actions. The applicability of Directive (EU) 2020/1828 to the representative actions brought against infringements by economic operators or providers of online marketplaces of provisions of this Regulation that harm or can harm the collective interests of consumers should start from the date of application of this Regulation. Until that date consumers should be able to rely on the applicability of Directive (EU) 2020/1828 in line with point 8 of Annex I of that Directive.*

- (65) In order to facilitate the effective and consistent application of the general safety requirement set out in this Regulation, it is important to make use of European standards covering certain products and risks. *European standards, the references of which have been published in accordance with Directive 2001/95/EC, should continue providing a presumption of conformity with the general safety requirement set out in this Regulation. Standardisation requests issued by the Commission in accordance with Directive 2001/95/EC should be deemed standardisation requests issued in accordance with this Regulation. In case different risks or risk categories are covered by the same standard, the conformity of a product with the part of the standard covering the relevant risk or risk category would also give to the product itself presumption of safety as far as the relevant risk or risk category is concerned.*
- (66) Where the Commission identifies a need for a European standard ensuring compliance of certain products with the general safety requirement under this Regulation, it should apply the relevant provisions of Regulation (EU) No 1025/2012 of the European Parliament and of the Council<sup>12</sup> to request one or several European standardisation organisations to either draft or identify a standard which is suitable to ensure that products which conform to it are presumed to be safe.
- (66a) Products could present different risks for different genders and standardisation activities should take this into account to avoid discrepancies in terms of safety and therefore a gender safety gap. The Gender Responsive Standards Declaration outlines several actions that national standards bodies and standards developing organisations should include in their gender action plan for gender responsive standards and standards development, in order to achieve gender balanced, representative and inclusive standards.*

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<sup>12</sup> Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14. 11. 2012, p. 12).

- (67) Certain provisions of Regulation (EU) 1025/2012 should be amended to take the specificities of this Regulation into account, and in particular the need to define the specific safety requirements under this Regulation before launching the request to the European standardisation organisation.
- (68) Together with the adaptation of Regulation (EU) 1025/2012, a specific procedure for the adoption of the specific safety requirements with the assistance of the specialised Committee provided for by this Regulation should be introduced.
- (69) █
- (69a) *In the absence of European standards, the law of the Member State where the product is made available on the market laying down health and safety requirements should comply with Union law, in particular Articles 34 and 36 of the TFEU.***
- (70) The Union should be able to cooperate and to exchange information related to product safety with regulatory authorities of third countries or international organisations within the framework of agreements concluded between the *Union and third countries or international organisations or of arrangements concluded between the Commission and authorities of third countries or international organisations, also with a view to preventing the circulation of dangerous products on the Union market.* Such cooperation and exchange of information should respect confidentiality and personal data protection rules of the Union. *Personal data should only be transferred to the extent that such exchange is necessary for the sole purpose of the protection of consumers' health or safety.*



- (70a) *Systematic exchange of information between the Commission and third countries or international organisations on the safety of consumer products and on preventive, restrictive and corrective measures should be based on reciprocity, which entails an equivalent but not necessarily identical exchange of information for mutual benefit. An exchange of information with a country producing goods destined to the Union market might consist in the Commission sending selected information from the Safety Gate Rapid Alert System related to products originating from this partner country. In exchange, this third country might send information on the follow-up measures taken on the basis of the notifications received. Such cooperation might contribute to the objective of stopping dangerous products at the source and preventing them from reaching the Union market.*
- (71) In order to play a significant deterrent effect for economic operators and, *where applicable, providers of* online marketplaces to prevent the placing of dangerous products on the market, penalties should be adequate to the type of infringement, to the possible advantage for the economic operator or *providers* online marketplace and to the type and gravity of the injury suffered by the consumer. ■ *Penalties should be effective, proportionate and dissuasive.*
- (71a) *The Commission should carry out an evaluation on the implementation of the penalties laid down under this Regulation as to their effectiveness and deterrent effects, and, if appropriate adopt a legislative proposal as to their enforcement.*
- (72) When imposing penalties, due regard should be given to the nature, gravity and duration of the infringement in question. The imposition of penalties should be proportionate and should comply with Union and national law, including with applicable procedural safeguards and with the principles of the Charter of fundamental rights.
- (73) ■
- (74) ■
- (75) ■

- (76) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to adopt the specific safety requirements, to determine the output indicators on the basis of which Member States have to communicate data concerning the implementation of this Regulation, to take measures as regards *Union action against* products presenting a serious risk, to adopt the modalities for the sending of information by consumers in the Safety Gate portal, to set out the requirements for registration of products for recall purposes and to adopt the template for a recall notice. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>13</sup>.
- (77) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the health and safety of consumers, imperative grounds of urgency so require.

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<sup>13</sup> Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

(78) In order to maintain a high level of health and safety of consumers, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in respect of the identification and traceability of products bearing a potential serious risk to health and safety ***and of the functioning of the Safety Gate Rapid Alert System, in particular to adopt the modalities and procedures for the exchange of information regarding measures communicated through the Safety Gate Rapid Alert System and criteria to assess the level of risk.*** It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making<sup>14</sup>. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(78a) ***In order to allow economic operators and providers of online marketplaces, sufficient time to adapt to the requirements of this Regulation, including information requirements, it is necessary to provide for a sufficient transitional period after the entry into force of this regulation during which products covered by Directive 2001/95/EC which are in conformity with that Directive may still be placed on the market. Member States should therefore not impede the making available on the market of such products, including offers for sale.***

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<sup>14</sup> OJ L 123, 12.5.2016, p. 1.

- (79) Since the objectives of this Regulation, namely to ensure a consistent, high level of consumer health and safety protection while preserving the unity of the Single market, cannot be sufficiently achieved by the Member States given the need for a high degree of collaboration and coherent action between Member States' competent authorities and for a mechanism to quickly and efficiently exchange information on dangerous products in the Union but can rather, by reason of the Union-wide character of the problem, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (80) *Where, for the purposes of this Regulation, it is necessary to process personal data, such processing should be carried out in accordance with Union law on the protection of personal data. Any processing of personal data under this Regulation is subject to Regulation (EU) 2016/679, Regulation (EU) 2018/1725 and Directive 2002/58/EC, as applicable.* When consumers report a product in the Safety Gate, only those personal data will be stored that are necessary to report the dangerous product and for a period not exceeding five years after such data have been encoded. Manufacturers and importers should hold the register of consumer complaints only as long as it is necessary for the purpose of this Regulation. Manufacturers and importers, when they are natural persons should disclose their names to ensure that the consumer is able to identify the product for purpose of traceability.
- (81) The European Data Protection Supervisor was consulted in accordance with Article 42 of Regulation (EU) 2018/1725 and delivered an opinion on XX XXXX.<sup>15</sup>

HAVE ADOPTED THIS REGULATION:

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<sup>15</sup> ...

## CHAPTER I

### General provisions

#### *Article 1*

##### *Subject matter*

- 1. The objective of this Regulation is to improve the functioning of the internal market while providing for a high level of consumer protection.***
2. This Regulation lays down essential rules on the safety of consumer products placed or made available on the market.

#### *Article 2*

##### *Scope*

1. This Regulation shall apply to products defined in Article 3(1), placed or made available on the market in so far as there are no specific provisions with the same objective in rules of Union law which regulate the safety of the products concerned.

Where products are subject to specific safety requirements imposed by Union legislation, this Regulation shall apply only to the aspects and risks or categories of risks not covered by those requirements.

In *regard to* products subject to specific requirements imposed by Union harmonisation legislation as defined in Article 3(25),

- (a) Chapter II shall not apply insofar as the risks or categories of risks covered by Union harmonisation legislation are concerned;
- (b) Chapter III, Section 1, Chapters V and VII, Chapters IX to XI shall not apply.

2. This Regulation shall not apply to:

- (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;
- (i) antiques.

3. This Regulation shall apply to products [placed or] made available on the market whether new, used, repaired or reconditioned. It shall not apply to products to be repaired or reconditioned prior to being used where those products are made available on the market ***and clearly marked*** as such.
4. This Regulation is without prejudice to the rules laid down by Union law on consumer protection.
5. ***This Regulation shall be implemented taking due account of the precautionary principle.***

### *Article 3*

#### *Definitions*

For the purposes of this Regulation the following definitions apply:

1. ‘product’ means 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;
2. ‘safe product’ means 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 health and safety of consumers;
3. ‘dangerous product’ means any product which does not conform to the definition of ‘safe product’;

4. ‘risk’ means the combination of the probability of an occurrence of a hazard causing harm and the degree of severity of that harm;
5. ‘serious risk’ means 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;
6. ‘making available on the market’ means any 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;
7. ‘placing on the market’ means the first making available of a product on the Union market;
8. ‘manufacturer’ means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under its name or trademark;
9. ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his or her behalf in relation to specified tasks *with regard to the manufacturer’s obligations under this Regulation*;
10. ‘importer’ means any natural or legal person established within the Union who places a product from a third country on the Union market;



11. ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;
12. ‘fulfilment service provider’ means any natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved, excluding postal services as defined in Article 2, point 1 of Directive 97/67/EC of the European Parliament and of the Council<sup>16</sup>, parcel delivery services as defined in Article 2, point 2 of Regulation (EU) 2018/644 of the European Parliament and of the Council<sup>17</sup>, and any other postal services or freight transport services;
13. ‘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, making them available on the market in accordance with this Regulation;
14. ‘*provider of an online marketplace*’ means a provider of an intermediary service using *an online interface*, which allows consumers to conclude distance contracts with ■ traders ■ for the sale of products.
15. ‘online interface’ means any software, including a website, part of a website or an application, *including mobile applications*;

(15a) ‘*distance contract*’ means a distance contract as defined in Article 2, point (7), of Directive 2011/83/EU;

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<sup>16</sup> Directive 97/67/EC of the European Parliament and of the Council of 15 December 1997 on common rules for the development of the internal market of Community postal services and the improvement of quality of service (OJ L 15, 21. 1. 1998, p. 14).

<sup>17</sup> Regulation (EU) 2018/644 of the European Parliament and of the Council of 18 April 2018 on cross-border parcel delivery services (OJ L 112, 2. 5. 2018, p. 19).

*(15a) ‘consumer’ means any natural person who acts for purposes which are outside that person’s trade, business, craft or profession;*

*(15c) ‘trader’ means any natural person, or any legal person irrespective of whether privately or publicly owned, who is acting, including through any person acting in his or her name or on his or her behalf, for purposes relating to his or her trade, business, craft or profession;*

16. █

17. ‘European standard’ means a European standard as defined in Article 2(1), point (b) of Regulation (EU) No 1025/2012;

18. ‘International standard’ means an international standard as defined in Article 2(1), point (a) of Regulation (EU) No 1025/2012;

19. ‘National standard’ means a national standard as defined in Article 2(1), point (d) of Regulation (EU) No 1025/2012;

20. ‘European standardisation organisation’ means a European standardisation organisation as listed in Annex 1 to Regulation (EU) No 1025/2012;

21. ‘market surveillance’ means the activities carried out and measures taken by market surveillance authorities to ensure that products comply with the requirements set out in this Regulation;

22. ‘market surveillance authority’ means an authority designated by a Member State under Article 10 of Regulation (EU) 2019/1020 as responsible for organising and carrying out market surveillance in the territory of that Member State;

23. 'recall' means any measure aimed at achieving the return of a product that has already been made available to the consumer;
24. 'withdrawal' means any measure aimed at preventing a product in the supply chain from being made available on the market;
25. 'Union harmonisation legislation' means Union legislation listed in Annex I to Regulation (EU) 2019/1020 and any other Union legislation harmonising the conditions for the marketing of products to which that Regulation applies.

*(25a) 'antiques' means products, such as collectible objects and works of art, in relation to which consumers cannot reasonably expect that they fulfil state-of-the-art safety standards.*

#### *Article 4*

##### *Distance sales*

1. 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 several Member State(s).
2. █

## CHAPTER II

### Safety requirements

#### *Article 5*

#### *General safety requirement*

Economic operators shall [place or] make available on the Union market only safe products.

#### *Article 5a*

#### *Aspects for assessing the safety of products*

- 1. *When assessing whether a product is safe, the following aspects shall be taken in particular into account:***
  - (a) the characteristics of the product, including its design, technical features, composition, packaging, instructions for assembly and, where applicable, for installation, use and maintenance;***
  - (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;***
  - (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;***

- (d) the presentation of the product, the labelling, including the labelling regarding age suitability for children, any warnings and instructions for its safe use and disposal, and any other indication or information regarding the product;*
- (e) the categories of consumers using the product, in particular by assessing the risk for vulnerable consumers such as children, older people and persons with disabilities, as well as the impact of gender differences on health and safety;*
- (f) the appearance of the product where it is likely to make consumers use the product in a way different from what it was designed for, and in particular:
  - (i) where a product, although not foodstuff, resembles foodstuff and is likely to be confused with foodstuff due to its form, odour, colour, appearance, packaging, labelling, volume, size or other characteristics and may therefore be placed in the mouth, sucked or ingested by the consumer, especially by children;*
  - (ii) where a product, although not designed or not intended for use by children, is likely to be used by children or resembles an object commonly recognized as appealing to or intended for use by children , because of its design, packaging and characteristics;**
- (h) when required by the nature of product, the appropriate cybersecurity features necessary to protect the product against external influences, including malicious third parties, when such an influence may have an impact on the safety of the product, including the possible loss of interconnection;*
- (i) when required by the nature of the product, the evolving, learning and predictive functionalities of a product.*

2. ***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 not to be safe.***

Article 6

***Presumption of conformity with the general safety requirement***

1. For the purpose of this Regulation, a product shall be presumed to be in conformity with the general safety requirement laid down in Article 5 in the following cases:
- (a) if it conforms to relevant European standards or parts thereof as far as the risks and risk categories covered ***by those standards*** are concerned, the references of which have been published in the Official Journal of the European Union in accordance with Article 10(7) of Regulation (EU) No **1025/2012**; ***or***
  - (b) in the absence of ***the*** European standards referred to in point (a), ***if the product conforms to national requirements***, as regards the risks ***and risk categories*** covered by health and safety requirements laid down in the law of the Member State ***it*** is made available on the market, ***provided that such law is in compliance with Union law***.
2. The Commission shall adopt implementing acts determining the specific safety requirements ***to be covered by European standards in order*** to ensure that products which conform to ***these*** European standards satisfy the general safety requirement laid down in Article 5. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 42(3).

3. However, presumption of *conformity with the general safety requirement* under paragraph 1 shall not prevent market surveillance authorities from taking *all appropriate measures* under this Regulation where there is evidence that, despite such *presumption*, the product is dangerous.

#### Article 7

*Additional elements to be taken into account* for assessing the safety of products

1.

For the purpose of *Article 5a and where the presumption of safety under Article 6 does not apply*, when assessing whether a product is safe, the following elements shall be taken *in particular* into account, *when available*:

- (a) European standards other than those the references of which have been published in the Official Journal of the European Union in accordance with Article 10(7) of Regulation (EU) 1025/2012;
- (b) international standards;
- (c) international agreements;
- (d) voluntary certification schemes or similar third-party conformity assessment frameworks, in particular those conceived to support Union legislation;
- (e) Commission recommendations or guidelines on product safety assessment;
- (f) national standards drawn up in the Member State in which the product is made available;
- (g) the state of the art and technology, including the opinion of recognized scientific bodies and expert committees;
- (h) product safety codes of good practice in force in the sector concerned;

- (i) reasonable consumer expectations concerning safety;
- (j) safety requirements adopted in accordance with Article 6(2).

2. █

## CHAPTER III

### Obligations of economic operators

#### Section 1

##### *Article 8*

##### *Obligations of manufacturers*

1. When placing their products on the market, manufacturers shall ensure that these products have been designed and manufactured in accordance with the general safety requirement laid down in Article 5.
2. █
3. █
4. ***Before placing a product on the market, manufacturers shall carry out an internal risk analysis and draw up a technical documentation containing at least a general description of the product and its essential properties 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) *[deleted]*
- (b) *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;*
- (c) *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. ■*

Where any of the European standards, health and safety requirements or elements referred to in Article 6(1) or Article 7 have been only partly applied, the parts which have been applied shall be identified.

5. Manufacturers shall *ensure that* the technical documentation *referred to in paragraph 4 is up to date. They shall keep it* for a period of ten years after the product has been placed on the market *at the disposal of* the market surveillance authorities, upon request.
  - 5a. *Manufacturers shall ensure that procedures are in place for products produced in series to remain in conformity with the general safety requirement laid down in Article 5.*
6. Manufacturers shall ensure that their products bear a type, batch or serial number or other element allowing the identification of the product which is easily visible and legible for consumers, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product.

7. Manufacturers shall indicate their name, *their* registered trade name or registered trade mark, *their postal and electronic address and, where different*, the postal *or* electronic address of *the single contact point* at which they can be contacted. *This information shall be placed* on the product or, where that is not possible, on its packaging or in a document accompanying the product. █
8. Manufacturers shall ensure that their product is accompanied by *clear* instructions and safety information in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available. This requirement shall not apply where the product can be used safely and as intended by the manufacturer without such instructions and safety information.
9. █
10. Manufacturers who consider or have reason to believe, on the basis of █ the information in their possession, that a product which they have placed on █ the market is *a dangerous product*, shall immediately take the corrective █ measures necessary to *effectively* bring the product █ into conformity, including a withdrawal or recall, as appropriate.
- 10a. When the product referred to in paragraph 10 is dangerous, manufacturers shall immediately inform consumers, in accordance with Articles 33 or 34. Manufacturers shall, via the Safety Business Gateway referred to in Article 25, immediately inform the market surveillance authorities of the Member States in which the product has been made available on the market. They shall give details, in particular, of the risk to health and safety of consumers and of any corrective measure already taken, and if available, of the quantity, by Member State, of products still circulating in the market.*
11. █

- 11a. The Commission shall ensure that the information meant to alert consumers can be provided by manufacturers via the Safety Business Gateway referred to in Article 25 and is made available to consumers on the Safety Gate Portal without undue delay.*
- 11b. Manufacturers shall ensure that other economic operators, responsible persons, and providers of online marketplaces in the concerned supply chain are kept informed in a timely manner of any safety issue that they have identified.*
- 11c. Manufacturers shall make publicly available communication channels such as a telephone number, electronic address or dedicated section of their website, taking into account accessibility needs for persons with disabilities, allowing consumers to file complaints and to inform them of any accident or safety issue they have experienced with the product.*
- 11d. Manufacturers shall investigate complaints and information on accidents received that concern the safety of products they [placed or] made available on the market and which have been alleged as dangerous by the complainant, and shall keep an internal register of those complaints as well as of product recalls and any corrective measures taken to bring the product into conformity.*
- 11e. Personal data stored in the internal register of complaints shall only be those personal data that are necessary for the manufacturer to investigate the complaint about an alleged dangerous product. Such data shall only be kept as long as it is necessary for the purpose of investigation and no longer than five years after they have been encoded.*

*Article 9*  
*Obligations of authorised representatives*

1. A manufacturer may, by a written mandate, appoint an authorised representative.
2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. ***It shall provide a copy of the mandate to the market surveillance authorities upon request.*** The mandate shall allow the authorised representative to perform at least the following tasks:
  - (a) ***providing*** a market surveillance authority, upon its reasoned request, with all information and documentation necessary to demonstrate the safety of the product in an official language which can be understood by that authority;
  - (b) where ***the authorised representative has*** a reason to believe that a product in question ***is dangerous, informing*** the manufacturer;
  - (ba) ***informing the competent national authorities about any action taken to eliminate the risks posed by products covered by their mandate through a notification in the Safety Business Gateway referred to in Article 25, in case that the information has not been already provided by the manufacturer or upon instruction of the manufacturer;***
  - (c) ***cooperating*** with the competent national authorities, at their request, on any action taken to ***effectively*** eliminate the risks posed by products covered by their mandate.

*Article 10*  
*Obligations of importers*

1. Before placing a product on the market importers shall ensure that the product is compliant with the general safety requirement laid down in Article 5 and that the manufacturer has complied with the requirements set out in Article 8(4), (6) and (7).
2. Where an importer considers or has reason to believe, *on the basis of the information in their possession*, that a product is not in conformity with Article 5 and Article 8(4), (6) and (7), *the importer* shall not place the product on the market until it has been brought into conformity. Furthermore, where the product is *dangerous*, the importer shall *immediately* inform the manufacturer and ensure that the market surveillance authorities are informed *through the Safety Business Gateway referred to in Article 25*.
3. Importers shall indicate their name, *their* registered trade name or registered trade mark, *their postal and electronic address and, where different*, the postal *or* electronic address *of the single contact point* at which they can be contacted. *This information shall be placed* on the product or, where that is not possible, on its packaging or in a document accompanying the product. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.
4. Importers shall ensure that the product they imported is accompanied by *clear* instructions and safety information in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available, except where the product can be used safely and as intended by the manufacturer without such instructions and safety information.
5. Importers shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardize its conformity with the general safety requirement laid down in Article 5 and its conformity with Article 8(6) and (7).

6. ■

Importers shall *verify whether* the communication channels referred to in Article 8(11c), second subparagraph, are *publicly* available to consumers allowing them to present complaints and communicate any accident or safety issue they have experienced with the product. If such channels are not available the importer shall provide for them, *taking into account accessibility needs for persons with disabilities*.

Importers shall investigate complaints *and information on accidents received that concern the safety of* products they made available on the market, *which have been alleged as dangerous by the complainant*, and file *those* complaints, as well as products recalls *and any corrective measures taken to bring the product into conformity*, in the register referred to in Article 8(11b), *second* subparagraph, or in their own *internal* register. Importers shall keep the manufacturer, *distributors and, where relevant, fulfilment service providers and providers of online marketplaces* informed *in a timely manner* of the investigation performed and of the results of the investigation.

■

7. Importers shall cooperate with market surveillance authorities and the manufacturer to ensure that a product is safe.

8. Importers who consider or have reason to believe, on the basis of the information in their possession, that a product which they have placed on the market is *dangerous* shall immediately inform the manufacturer and ensure that the corrective measures necessary to bring *effectively* the product into conformity are adopted including withdrawal or recall, as appropriate. In case such measures have not been adopted, the importer shall *immediately* adopt them. ■

- 8a. *Where the product is dangerous, importers shall ensure that consumers are immediately informed thereof in accordance with Article 33 or 34. Importers shall, via the Safety Business Gateway referred to in Article 25, immediately inform the market surveillance authorities of the Member States in which the product has been made available on the market. They shall give details, in particular, of the risk to health and safety of consumers and of any corrective measure already taken, and if available of the quantity, by Member State, of products still circulating in the market.*
9. Importers shall keep the *copy of* technical documentation referred to in Article 8(4), *first subparagraph*, for a period of 10 years after they have placed the product on the market *at the disposal of* the market surveillance authorities *and ensure that the documents referred to in Article 8(4), as applicable, can be made available to those authorities*, upon request.
- 9a. *Personal data stored in the register of complaints shall only be those personal data that are necessary for the importer to investigate the complaint about an alleged dangerous product. Such data shall only be kept as long as it is necessary for the purpose of investigation and no longer than five years after they have been encoded.*

*Article 11*  
*Obligations of distributors*

1. Before making a product available on the market, distributors shall verify that the manufacturer and, *where applicable*, the importer have complied with the requirements set out in Article 8(6), (7) and (8) and Article 10(3) and (4), as applicable.
2. Distributors shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardize its conformity with the general safety requirement laid down in Article 5 and its conformity with Article 8(6), (7) and (8) and Article 10(3) and (4), as applicable.
3. Distributors who consider or have reason to believe, on the basis of the information in their possession, that a product is not in conformity with **Article 5, Article 8(6) to (8), and Article 10(3) and (4)**, shall not make the product available on the market *unless* it has been brought into conformity. Furthermore, where the product is *dangerous*, the distributor shall immediately inform the manufacturer or the importer, as applicable, *and ensure* that, *via* the Safety Business Gateway referred to in Article 25, the market surveillance authorities are informed.
4. Distributors who consider or have reason to believe, on the basis of the information in their possession, that a product which they have made available on the market is *dangerous* or is not in conformity with Article 8(6), (7) and (8) and Article 10(3) and (4), as applicable, shall ensure that the corrective measures necessary to bring *effectively* the product into conformity are adopted, including withdrawal or recall, as appropriate. ■



**4a.** *When the product referred to in paragraph 4 is dangerous, distributors shall immediately inform the manufacturer or the importer, as applicable, and shall ensure that the market surveillance authorities of the Member States in which the product has been made available are immediately informed, via the Safety Business Gateway referred to in Article 25, with the appropriate details available to them of the risk to health and safety of consumers, of the number of products involved and of any corrective measure already taken.*

#### Article 12

##### *Cases in which obligations of manufacturers apply to other persons*

**-1a.** *A natural or legal person shall be considered to be a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 8 where that natural or legal person places a product on the market under the natural or legal person's name or trademark.*

1. A natural or legal person, other than the manufacturer, that substantially modifies the product, shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 8 for the part of the product affected by the modification or for the entire product if the substantial modification has an impact on its safety.
2. A modification *of a product, by physical or digital means*, shall be deemed to be substantial where *it has an impact on the safety of the product and* the three following criteria are met:
  - (a) the modification changes **█** the product in a manner which was not foreseen in the initial risk assessment of the product;

- (b) the nature of the hazard has changed, *a new hazard has been created* or the level of risk has increased because of the modification;
- (c) the changes have not been made by the *consumers themselves or on their behalf* for their own use.

### *Article 13*

#### *Internal processes for product safety*

*The economic operators shall ensure that they have internal processes for product safety in place, allowing them to comply **with the relevant requirements of this Regulation.***

### *Article 14*

#### *Cooperation of economic operators with market surveillance authorities*

1. Economic operators shall cooperate with market surveillance authorities regarding actions which could eliminate or mitigate risks that are presented by *the relevant* products made available on the market **■**.
2. On request of a market surveillance authority, the economic operator shall provide all necessary information, and in particular:
  - (a) a full description of the risk presented by the product, *related complaints and known accidents*;
  - (b) a description of any corrective measure undertaken to address the risk.

3. On request, the economic operators shall also identify and communicate the following *relevant traceability* information *for the product*:
  - (a) any economic operator who has supplied them with the product, *or with a part, a component or any software embedded into the product*;
  - (b) any economic operator to whom they have supplied the product.
4. Economic operators shall be able to present the information referred to in █ paragraph 2 for a period of ten years after they have been supplied with the product and for a period of ten years after they have supplied the product, where relevant.
  - 4a. *Economic operators shall be able to present the information referred to in paragraph 3 for a period of six years after they have been supplied with the product and for a period of six years after they have supplied the product, where relevant.*
5. █ Market surveillance authorities may request the economic operators to submit regular progress reports and *may* decide whether or when the corrective measure can be considered completed.

## Article 15

### *Responsible person for products placed on the Union market*

1. ***A product covered by this Regulation may be placed on the market only if there is an economic operator established in the Union who is responsible for the tasks set out in Article 4(3) of Regulation (EU) 2019/1020 in respect to that product. Article 4(2) and (3) of Regulation (EU) 2019/1020 shall apply to products covered by this Regulation. For the purposes of this Regulation, references to "Union harmonisation legislation" and "applicable Union harmonisation legislation" in Article 4(3) of Regulation (EU) 2019/1020 shall be read as "this Regulation".***
  
2. ***Without prejudice to any obligations of economic operators under this Regulation, in addition to the tasks referred to in Article 4(3) of Regulation (EU) 2019/1020, and to ensure the safety of the product it is responsible for, where appropriate with regard to the possible risks related to a product, the economic operator referred to in paragraph 1 shall regularly check:***
  - (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).***

***The economic operator referred to in paragraph (1) shall provide, upon request of the market surveillance authorities, documented evidence of the checks performed.***
  
3. The name, registered trade name or registered trade mark, and contact details, including the postal and electronic address, of the economic operator referred to in ***paragraph 1*** shall be indicated on the product or on its packaging, the parcel or an accompanying document.

## Article 16

### *Information to economic operators*

1. ***The Commission shall provide economic operators, free of charge, with general information with respect to this Regulation.***
2. Member States shall ***provide*** economic operators, at their request and free of charge, with ***specific*** information with respect to the implementation of this Regulation ***at national level and national rules on product safety applicable to products covered by this Regulation.*** ***For that purpose, Article 9(1) and (4) of Regulation (EU) 2019/515 shall apply.***

***The Commission shall adopt specific guidelines for economic operators, with particular regard to the needs of those that qualify as SMEs, including micro-enterprises, on how to fulfil the obligations laid down in this Regulation.***

## Article 17

### ***Specific traceability requirements for certain products, categories or groups of products***

1. For certain products, categories or groups of products, which are susceptible to bear a serious risk to health and safety of consumers, based on accidents registered in the Safety Business Gateway, the Safety Gate statistics, the results of the joint activities on product safety and other relevant indicators or evidence, ***and after consulting the Consumer Safety Network referred to in Article 28, relevant expert groups and relevant stakeholders,*** the Commission may ***set up a system of traceability to which*** economic operators who **█** make available those products on the market ***shall*** adhere **█** .

2. The system of traceability shall consist in the collection and storage of data, including by electronic means, enabling the identification of the product, its components or of the economic operators involved in its supply chain, as well as in modalities to display and to **access *those*** data, including placement of a data carrier on the product, its packaging or accompanying documents.
3. The Commission is empowered to adopt delegated acts in accordance with Article 41 to supplement this Regulation by:
  - (a) determining the products, categories or groups of products or components susceptible to bear a serious risk to health and safety of persons as referred to in paragraph 1. The Commission shall state in the delegated acts concerned if it has used the risk analysis methodology provided for in Commission Decision (EU) 2019/417<sup>18</sup> or, if that methodology is not appropriate for the product concerned, it shall give a detailed description of the methodology used;
  - (b) specifying the type of data, which economic operators shall collect and store by means of the traceability system referred to in paragraph 2;
  - (c) ***specifying*** the modalities to display and to access data, including placement of a data carrier on the product, its packaging or accompanying documents as referred to in paragraph 2.
  - (d) ***specifying the actors that shall have access to the data referred to in point (b) and to what data they shall have access, including consumers, economic operators, providers of online marketplaces, competent national authorities, the Commission, and public interest organisations, or any organisation acting on their behalf.***

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<sup>18</sup> Commission Implementing Decision (EU) 2019/417 of 8 November 2018 laying down guidelines for the management of the European Union Rapid Information System ‘RAPEX’ established under Article 12 of Directive 2001/95/EC on general product safety and its notification system (OJ L 73, 15.3.2019, p. 121).

- 3a. *Market surveillance authorities, consumers, economic operators and other relevant actors shall have free access to the data referred to in paragraph 3 based on their respective access rights set out in the applicable delegated act adopted pursuant to paragraph 3, point (d).*
4. When adopting the measures referred to in paragraph 3, the Commission shall take into account:
- (a) the cost-effectiveness of the measures, including their impact on businesses, in particular small and medium-sized enterprises;
  - (aa) *an adequate delay in order for economic operators to prepare for these measures;*
  - (b) the compatibility *and interoperability with other product* traceability systems *already set up* at Union or at international level.

## Section 2

### Article 18

#### *Obligations of economic operators in case of distance sales*

Where products are made available on the market online or through other means of distance sales by **■** economic operators, the relevant offer of the product 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 within the meaning of Article 15(1) **of this Regulation or Article 4(1) of Regulation (EU) 2019/1020**;
- (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 accordance with this Regulation or the applicable Union harmonisation legislation in a language which can be easily understood by consumers.



## Article 19

### *Obligations of economic operators in case of accidents **related to safety of products***

1. The manufacturer shall ensure that, through the Safety Business Gateway referred to in Article 25, an accident caused by a product [placed or] made available on the market is notified, **without undue delay** from the moment it knows about the accident, to the competent authorities of the Member State where the accident has occurred. The notification shall include the type and identification number of the product as well as the circumstances of the accident, if known. The manufacturer shall notify, upon request, to the competent authorities any other relevant information.
  - 1a. ***For the purpose of paragraph 1, the manufacturer shall notify the occurrences associated with the use of a product that 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.***
2. The importers and the distributors which have knowledge of an accident caused by a product that they placed or made available on the market shall **without undue delay** inform the manufacturer, which can **proceed to the notification in accordance with paragraph 1 or** instruct the importer or one of the distributors to proceed to **such** notification.
3. ***Where the manufacturer of the product is not established in the Union, the responsible person within the meaning of Article 15(1) of this Regulation or Article 4(1) of Regulation (EU) 2019/1020 which has knowledge of an accident shall ensure that the notification is done.***

*Article 19a*  
*Information in electronic format*

1. *Without prejudice to Articles 8(6), (7) and (8), Article 10(3) and Article 15(3), and the relevant provisions in the Union harmonisation legislation, economic operators may additionally make the information referred to in those Articles 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. That information shall be in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available, and in accessible formats for persons with disabilities.*

CHAPTER IV  
Online marketplaces

*Article 20*

*Specific obligations of providers of online marketplaces related to product safety*

1. *Without prejudice to the general obligations provided for in Article 11 of Regulation (EU) [.../...] on a Single Market for Digital Services (Digital Services Act) and amending Directive 2000/31/EC, providers of online marketplaces shall designate a single point of contact allowing for direct communication, by electronic means, with Member States' market surveillance authorities in relation to product safety issues, in particular for the purpose of notifying orders issued pursuant to paragraph 2. ■*

*Providers of onlinemarketplaces shall register with the Safety Gate portal and indicate on the portal the information concerning their single contact point.*

- 1a. *Without prejudice to the general obligations provided for in Article 12 of Regulation (EU) [.../...] on a Single Market for Digital Services (Digital Services Act) and amending Directive 2000/31/EC, providers of online marketplaces shall designate a single point of contact to enable consumers to communicate directly and rapidly with them in relation to product safety issues.*
- 1b. *Providers of online marketplaces shall ensure that they have internal processes for product safety in place in order to comply with the relevant requirements of this Regulation without undue delay.*
2. As *regards* powers conferred by Member States in accordance to Article 14 of Regulation (EU) 2019/1020 are concerned, Member States shall confer on their market surveillance authorities the *necessary power to impose on the providers of online marketplaces the removal of* specific content referring to *an offer of* a dangerous product from *their* online interface, to disable access to it or to display an explicit warning . Such orders shall *be issued in accordance with the minimum conditions set out in Article 9(2) of Regulation (EU) [.../...] on a Single Market for Digital Services (Digital Services Act) and amending Directive 2000/31/EC.*

*Providers of online marketplaces shall take the necessary measures to receive and process the orders issued pursuant to this paragraph and they shall act without undue delay, and in any event within two working days from receipt of the order. They shall inform the issuing market surveillance authority of the effect given to the order by electronic means using the contacts of the market surveillance authority published in the Safety Gate Portal.*

- 2c. *Orders issued pursuant to paragraph 2 may require, during the period indicated in the order, the provider of online marketplace to remove from its online interface all identical content referring to an offer of the dangerous product in question, to disable access to it or to display an explicit warning, provided that the search for the content concerned is limited to the information identified in the order and does not require the provider to carry out an independent assessment of that content, and that the search and the removal can be carried out in a proportionate manner by reliable automated tools.*

3. **Providers of** online marketplaces shall take into account regular information on dangerous products notified by the market surveillance authorities in line with Article 24, received via the Safety Gate Portal, for the purpose of applying their voluntary measures aimed at detecting, identifying, removing or disabling access to the **■** content referring to *offers of dangerous products ■* on their marketplace, where applicable, **also by making use of the interoperable interface to the Safety Gate Portal in accordance with Article 23**. They shall inform the authority that made the notification to the Safety Gate of any action taken by using the contacts of the market surveillance authority published in the Safety Gate *Portal*.
- 3a. **For the purpose of compliance with Article 31(3) of Regulation (EU) [.../...] on a Single Market for Digital Services (Digital Services Act), regarding product safety, providers of online marketplaces shall use at least the Safety Gate Portal.**
4. **Providers of** online marketplaces shall **■** without undue delay, and in any event within *three* working days **process notices related to product safety issues with regard to the product offered for sale online through their services**, received in accordance with **■** Article 16 of Regulation (EU) [.../...] on a Single Market for Digital Services (Digital Service Act) and amending Directive 2000/31/EC.
5. For the purpose of **compliance with** the requirements of Article 31(1) and (2) of Regulation (EU) [.../...] on a Single Market for Digital Services (Digital Services Act) and amending Directive 2000/31/EC **as regards product safety information, providers of** online marketplaces shall design and organise their online interface in a way that enables traders **offering the product** to provide **at least** the following information for each product offered and ensures that it is displayed or otherwise made easily accessible by consumers on the product listing:
- (a) name, registered trade name or registered trade mark of the manufacturer, as well as the postal **and** electronic address at which **the manufacturer** can be contacted;
  - (b) where the manufacturer is not established in the Union, the name, **postal** and electronic address of the responsible person within the meaning of Article 15(1) of **this Regulation or Article 4(1) of Regulation (EU) 2019/1020**;

- (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 to accompany it in accordance with this Regulation or the applicable Union harmonisation legislation in a language which can be easily understood by consumers.

**5a.** *The internal processes referred to in paragraph 1b shall include mechanisms which enable traders to provide:*

- (a) *information in accordance with paragraph 5 of this Article including information on the manufacturer established in the Union or, where applicable, the responsible person, and*
- (b) *their self-certification committing to only offer products that comply with this Regulation and additional identification information, in accordance with Article 30(1) of the DSA, where applicable.*

**5b.** *For the purpose of compliance with Article 20 of Regulation (EU) [.../...] on a Single Market for Digital Services (Digital Services Act), regarding product safety, providers of online marketplaces shall suspend, for a reasonable period of time and after having issued a prior warning, the provision of their services to traders that frequently offer products which are non-compliant with this Regulation*

6. **Providers of** online marketplaces shall cooperate with the market surveillance authorities, **with traders** and with relevant economic operators to facilitate any action taken to eliminate or, if that is not possible, to mitigate the risks presented by a product that is or was offered **online** through their services.

***In particular, providers of online marketplaces shall:***

- (-a) ensure that, they provide appropriate and timely information to consumers including by:***
- (i) directly notifying all affected consumers who bought through their interfaces the relevant product in case of a product safety recall of which they have actual knowledge, or where certain information has to be brought to the attention of consumers to ensure the safe use of a product ('safety warning') [in accordance of Articles 33 and 34];***
  - (ii) publishing information on product safety recalls on their online interfaces;***
- (-aa) inform the relevant economic operator of the decision to remove or disable access to the content referring to an offer of a dangerous product.***
- (a) cooperate with market surveillance authorities and with relevant economic operators to ensure effective product recalls, including by abstaining from putting obstacles to product recalls;***
  - (b) immediately inform, via the Safety Business Gateway referred to in Article 25, about dangerous products of which they have actual knowledge that were offered on their online interfaces the market surveillance authorities of the Member States in which the relevant product has been made available with the appropriate details available to them of the risk to health and safety of consumers, of if available of the quantity by Member State of products still circulating in the market and of any corrective measure that, to their knowledge, has already been taken;***

- (ba) *cooperate with regard to accidents notified to them, including by:*
- (i) *informing the relevant traders and economic operators without delay about the information they received on accidents or safety issues, where they have knowledge that the product in question was offered by those traders via their interfaces;*
  - (ii) *notifying without undue delay through the Safety Business Gateway referred to in Article 25 of any accident, which they have been informed of [resulting in serious risk to or actual damage of the health or safety of a consumer] caused by a product made available on their marketplace and inform the manufacturer thereof;*
- (c) *cooperate* with law enforcement agencies at national and Union level, including the European Anti-Fraud Office, through regular and structured exchange of information on offers that have been removed on the basis of this Article by *providers of* online marketplaces;
- (d) *allow* access to their interfaces for the online tools operated by market surveillance authorities to identify dangerous products;
- (da) *cooperate in identifying, as far as possible, the supply chain of dangerous products by responding to data requests should relevant information not be publicly available;*
- (e) upon *a reasoned* request of the market surveillance authorities, when *providers of* online marketplaces or online sellers have put in place technical obstacles to the extraction of data from their online interfaces (data scraping), *allow the scraping of* such data *only* for product safety purposes based on the identification parameters provided by the requesting market surveillance authorities.

*For the purpose of points (d) and (e) of the second paragraph of this paragraph, Article 31 of this Regulation shall apply.*

## CHAPTER V

### Market surveillance and implementation

#### *Article 21*

#### *Market Surveillance*

1. **Article 10, Article 11(1) to (7), Articles 12 to 15, Article 16(1) to (5), Articles 18 and 19 and Articles 21 to 24 of Regulation (EU) 2019/1020 shall apply to products covered by this Regulation.**
2. For the purpose of this Regulation, Regulation (EU) 2019/1020 shall be applied as follows:
  - (a) references to ‘Union harmonisation legislation’, ‘**applicable Union harmonisation legislation**’, ‘**this Regulation and for the application of Union harmonisation legislation**’, ‘**the relevant Union harmonisation legislation**’ and ‘**Union harmonisation legislation or this Regulation**’ in **Articles 11, 13, 14 and 16, Articles 18 and 23** of Regulation (EU) 2019/1020 shall be read as references to ‘this Regulation’;
  - (b) reference to ‘that legislation and this Regulation’ in Article 11(1) point b of Regulation (EU) 2019/1020 shall be read as **reference to ‘this Regulation’**;
  - (c) references to ‘Network’ in **Articles 11 to 13 and Article 21** of Regulation (EU) 2019/1020 shall be read as references to ‘Network and Consumer Safety Network referred to in Article 28 of this Regulation’;
  - (d) references to ‘non-compliance’, ‘**non-compliances**’ and ‘**non-compliant**’ in **Article 11, Articles 13 to 16, Articles 22 and 23** of Regulation (EU) 2019/1020 shall be read as **references** to ‘failure to comply with this Regulation’;



- (e) the reference to ‘Article 41’ in Article 14(4), point (i) of Regulation (EU) 2019/1020 shall be read as reference to ‘Article 40 of this Regulation’:
- (f) the reference to ‘Article 20’ in Article 19(1) of Regulation (EU) 2019/1020 shall be read as reference to ‘Article 24 of this Regulation’.
3. Where a dangerous product has been identified, **market surveillance authorities may** request **from the manufacturer information on** other products, produced with the same procedure, containing the same components or being part of the same production batch, **which** are affected by the same risk.

4. █

#### *Article 22*

#### ***Reporting***

1. Member States shall communicate to the Commission, **two years after the adoption of the implementing act referred to in paragraph 2 and every year afterwards**, data concerning the **application** of this Regulation.

***Following the communication from the Member States, the Commission shall draw up a summary report annually and make it available to the public.***

2. The Commission, by means of implementing acts, shall determine the output indicators on the basis of which Member States have to communicate this data. Those implementing acts shall be adopted in accordance with the **examination** procedure referred to in Article 42(3).

## CHAPTER VI

### Safety Gate Rapid Alert System *and Safety Business Gateway*

#### *Article 23*

##### *Safety Gate Rapid Alert System*

1. The Commission shall further develop, **modernise** and maintain **the** rapid alert system for the exchange of information on corrective measures concerning dangerous products ('the Safety Gate **Rapid Alert System**'), **as well as enhance its efficiency**.
2. The Commission and the Member States shall have access to the Safety Gate **Rapid Alert System**. For that purpose, each Member State shall designate a single national contact point which shall **at least be responsible for the completeness check and the submission of notifications for validation by the Commission, as well as for communication with the Commission with regard to** the tasks provided for in Article 24(1) **to (2a) and (4) to (6)**.

***The Commission shall adopt implementing act specifying the roles and tasks of single national contact points. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 42(3).***

Article 24

*Notification through the Safety Gate **Rapid Alert System** of dangerous products*

1. Member States shall notify in the Safety Gate **Rapid Alert System** corrective measures taken by their authorities or by economic operators:
  - (a) on the basis of provisions of this Regulation in relation to **dangerous** products presenting a **serious** risk to the health and safety of consumers;
  - (b) on the basis of **Article 20** of Regulation (EU) 2019/1020;
- 1a. *Member States may also notify envisaged corrective measures in relation to products presenting a serious risk in the Safety Gate **Rapid Alert System** if they consider it necessary as regards to the urgency of the risk to the health or safety of consumers.*
2. *Without prejudice to paragraph 1, Member States shall inform the Commission about corrective measures taken by their authorities or by economic operators on the basis of this Regulation. The Commission shall forward this information to the other Member States. For that purpose, Member States may notify in the Safety Gate **Rapid Alert System** corrective measures taken by their authorities or by economic operators on the basis of **the provisions of this Regulation and the** provisions of Union harmonisation legislation and Regulation (EU) 2019/1020 in relation to products presenting a less than serious risk.*
- 2a. *The notification referred to in paragraph 1 shall be submitted in the Safety Gate **Rapid Alert System** by the national authorities without delay and in any case within four working days after the corrective measure is taken.*
3. *By four working days after receiving a **complete** notification, the Commission shall check whether it complies with this Article and with the requirements related to the operation of **the Safety Gate **Rapid Alert System**** defined by the Commission on the basis of paragraph 8, and transmit it to the other Member States if the requirements are complied with.*

4. Member States shall notify in the Safety Gate **Rapid Alert System** without *undue* delay any update, modification or withdrawal of the corrective measures referred in *paragraphs 1, 1a and 2*.
5. Where a Member State notifies corrective measures taken in relation to products presenting a serious risk, the other Member States shall notify in the Safety Gate **Rapid Alert System** *the corrective measures or other* actions taken subsequently in relation to the same products and any other relevant information, including the results of any tests or analyses carried out, *without undue delay and in any event no later than four working days after* the measures or actions *are taken*.
6. If the Commission identifies, *including on the basis of information received by consumers or consumer organisations*, products which are likely to present a serious risk and for which Member States have not submitted a notification in the Safety Gate **Rapid Alert System**, it shall inform the Member States. Member States shall undertake the appropriate verifications and, if they adopt measures, notify them in the Safety Gate **Rapid Alert System** in accordance with paragraph 1.
7. The Commission shall *implement the* interface *referred to in Article 20(5) of Regulation (EU) 2019/1020* between the information and communication system referred to in Article 34 of Regulation (EU) 2019/1020 and the Safety Gate **Rapid Alert System** to enable a draft Safety Gate notification to be triggered from that information and communication system *in order to avoid double data entry*.
8. The Commission shall adopt *delegated acts in accordance with Article 41 to supplement this Regulation by specifying*, in particular:
  - (a) the access to the system;
  - (b) the operation of the system;
  - (c) the information to be entered in the system;

- (d) the requirements notifications must meet;
- (e) *the* criteria to assess the level of risk. ■

#### *Article 25*

#### *Safety Business Gateway*

1. The Commission shall maintain a web portal enabling the economic operators ***and providers of online marketplaces*** to provide ***in an easy way*** market surveillance authorities and consumers with the information referred to in Articles [8(11), 9(2) point ***ba***), 10(8), 11(3), 11(4)] ***and Articles 19 and 20***.
2. The Commission shall draw up guidelines for the practical implementation of the Safety Business Gateway.

### CHAPTER VII

#### Commission role and enforcement coordination

#### *Article 26*

#### *Union action against products presenting a serious risk*

1. If the Commission becomes aware of a product, or a specific category or group of products presenting a serious risk to the health and safety of consumers, it may take any appropriate measures, either on its own initiative or upon request of Member States, by means of implementing acts, adapted to the gravity and urgency of the situation if, at one and the same time:

- (a) ■
- (b) the risk cannot be dealt with, in view of the nature of the safety issue posed by the product, category or group of products, in a manner compatible with the degree of gravity or urgency of the case, under other procedures laid down by the specific Union legislation applicable to the products concerned; and
- (c) the risk can be eliminated effectively only by adopting appropriate measures applicable at Union level, in order to ensure a consistent and high level of protection of the health and safety of consumers and the proper functioning of the internal market.

Those measures may include measures prohibiting, suspending or restricting the [placing or] making available on the market of such products or laying down special conditions for their *conformity assessment with regard to the safety requirement, as applicable, or marketing, such as representative sample testing of those products*, in order to ensure a high level of consumer safety protection.

*Member States shall take within their jurisdiction all necessary enforcement measures necessary to ensure the effective implementation of those implementing acts. The Commission shall be informed of the adoption of those enforcement measures by the competent authorities of the Member States concerned.*

*The Commission shall regularly evaluate the efficiency of the enforcement measures taken by Member States and inform the Consumer Safety Network referred to in Article 28.*

2. The implementing acts referred to in the paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 42(3). The implementing act shall determine the date, on which it will cease to apply.

3. On duly justified imperative grounds of urgency relating to the health and safety of consumers the Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 42(4).
4. The export from the Union of a product that has been prohibited to be [placed or] made available on the Union market pursuant to a measure adopted in accordance with paragraph 1 or 3 shall be prohibited, unless the measure expressly so permits *for duly justified reasons*.
5. Any Member State may submit a substantiated request to the Commission to examine the need for the adoption of a measure referred to in paragraph 1 or 3.

#### *Article 27*

##### ***Request of an opinion from the Commission on divergences in risk assessment.***

1. Products that have been deemed dangerous on the basis of a decision of a market surveillance authority in one Member State ***according to this Regulation*** shall be presumed dangerous by market surveillance authorities in other Member States.
2. Where market surveillance authorities in other Member States reach a different conclusion in terms of identification or level of the risk on the basis of their own investigation and risk assessment, ***any Member State may refer the matter to the Commission, which shall issue an opinion on the identification or on the level of the risk of the relevant product as appropriate without undue delay. Where the matter has not been referred to the Commission, the Commission may nevertheless issue an opinion on its own initiative. For the purpose of issuing that opinion, the Commission may ask for relevant information and documents and*** shall invite all Member States to express a recommendation.

3. █

4. The opinion shall be taken into due account by the Member States.
5. The Commission shall draw up guidelines for the practical implementation of this Article.
- 5a. ***The Commission shall periodically draw up a report on the application of this Article and present it to the Consumer Safety Network referred to in Article 28.***

#### *Article 28*

#### *Consumer Safety Network*

1. A European network of the authorities of the Member States competent for product safety ('Consumer Safety Network') ***is hereby established.***

***The purpose of the Consumer Safety Network shall be to serve as a platform for structured coordination and cooperation between authorities of the Member States and the Commission to enhance product safety in the Union.***

2. The Commission shall promote and take part in the operation of the Consumer Safety Network, in particular in the form of administrative cooperation.
3. The objective of ***the*** Consumer Safety Network shall be, in particular, to **■** :
  - (a) ***facilitate the regular*** exchange of information on risk assessments, dangerous products, test methods and results, ***standards, methodologies to collect data, interoperability of information and communication systems,*** recent scientific developments ***and use of new technologies*** as well as other aspects relevant for control activities;
  - (b) ***organise*** the establishment and execution of joint surveillance and testing projects, ***including in the context of e-commerce;***



- (c) ***promote*** the exchange of expertise and best practices and cooperation in training activities;
  - (d) ***improve*** cooperation at ***Union*** level with regard to the tracing, withdrawal and recall of dangerous products;
  - (e) ***facilitate*** enhanced ***and structured*** cooperation on product safety enforcement between Member States, in particular to facilitate the activities referred to in Article 30.
- (ea) ***facilitate the implementation of this Regulation.***

4. The Consumer Safety Network shall coordinate its action with the other existing Union activities ***related to market surveillance and consumer safety and, where relevant, shall cooperate and exchange information with other Union networks, groups and bodies.***

4a. ***The Consumer Safety Network shall adopt its work programme, which, inter alia, sets out the priorities for safety of the products covered by this Regulation, in the Union.***

***The Consumer Safety Network shall meet at regular intervals and, where necessary, at the duly justified request of the Commission or a Member State.***

***The Consumer Safety Network may invite experts and other third parties, including consumer organisations, to attend its meetings.***

5. The Consumer Safety Network shall be duly represented and ***regularly*** participate in the ***relevant*** activities of in the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020 and shall contribute to its activities in relation to product safety to ensure adequate coordination of market surveillance activities in both harmonised and non-harmonised areas.

## Article 29

### *Joint activities on product safety*

1. In the framework of the activities referred to in Article 28(3), point (b), market surveillance authorities may agree with other relevant authorities or with organisations representing economic operators or consumers to carry out activities aimed at ensuring safety and protection of consumers health with respect to specific categories of products [placed or] made available on the market, in particular categories of products that are often found to present a serious risk.
2. The **relevant** market surveillance authorities and the **parties referred to in paragraph 1** shall ensure that the agreement to carry out **such** activities does not lead to unfair competition between economic operators and does not affect the objectivity, independence and impartiality of the parties ■ .
  - 2a. ***The Commission shall organise on regular basis a joint activity whereby market surveillance authorities shall conduct inspections on products made available online or offline, acquired under a cover identity.***
3. A market surveillance authority may use any information resulting from the activities carried out as part of any investigation regarding the safety of products that it undertakes.
4. The market surveillance authority concerned ■ shall make the agreement on joint activities, including the names of the parties involved, available to the public **and shall enter that agreement in the information and communication system referred to in Article 34 of Regulation (EU) 2019/1020. The Commission shall make the agreement available on the Safety Gate Portal.**

Article 30

*Simultaneous coordinated control actions of market surveillance authorities ("Sweeps")*

1. **Concerned** market surveillance authorities **shall** conduct simultaneous coordinated control actions ("sweeps") of particular **products or** categories **of products** to check compliance with **■** this Regulation.
2. Unless otherwise agreed upon by the market surveillance authorities **involved**, sweeps shall be coordinated by the Commission. The coordinator of the sweep **shall**, where appropriate, make the aggregated results publicly available.
3. When conducting sweeps, the market surveillance authorities involved may use the investigation powers set out in Chapter V and any other powers conferred upon them by national law.
4. Market surveillance authorities may invite Commission officials, and other accompanying persons authorised by the Commission, to participate in sweeps.

## CHAPTER VIII

### Right to information and remedy

#### *Article 31*

#### *Information between **■** authorities and **general public***

1. Information available to the authorities of the Member States or to the Commission relating to measures on products presenting risks to consumer health and safety shall in general be made available to the public, in accordance with the requirements of transparency and without prejudice to the restrictions required for monitoring and investigation activities. In particular, the public shall have access to information on product identification, the nature of the risk and the measures taken. This information shall be provided in accessible formats for persons with disabilities.
2. Member States and the Commission shall take the necessary steps to ensure that their officials and agents are required *to protect* information obtained for the purposes of this Regulation which *is confidential in accordance with Union and national law*.
3. Protection of professional secrecy shall not prevent the dissemination to the competent authorities of Member States *and to the Commission* of information relevant for ensuring the effectiveness of market monitoring and surveillance activities. The authorities receiving information covered by professional secrecy shall ensure its protection *in accordance with Union and national law*.

4. Member States shall give consumers and other interested parties the opportunity to submit complaints to the competent authorities on product safety, on surveillance and control activities *related to specific products as well as on instances where remedies offered to consumers in case of product recalls are not satisfactory*. These complaints shall be followed up as appropriate. *The complainant shall receive appropriate information on the follow-up, in accordance with national law.*

#### Article 32

#### *Safety Gate portal*

1. For the purpose of Article 31(1) and Article 19 *and Article 20*, the Commission shall maintain a Safety Gate portal, providing the general public with free access to selected information notified in accordance with Article 24.
  - 1a. *The portal referred to in paragraph 1 shall have an interface intuitive for users and the information provided shall be easily accessible for general public, including for persons with disabilities.*
2. Consumers *and other interested parties* shall have the possibility to inform the Commission of products *that may present* a risk to consumer health and safety through a separate section of the Safety Gate portal. The Commission shall take **■** due consideration of the information received and, *after verification of its accuracy*, where appropriate *forward this information to the relevant Member States without undue delay to ensure that those complaints are followed-up as needed. The Commission shall inform consumers and other interested parties of its action.*

3. The Commission, by means of an implementing act, shall adopt the modalities for the sending of information by consumers in accordance with paragraph 2, as well as for the transmission of such information to the concerned national authorities for possible follow up. This implementing act shall be adopted in accordance with the examination procedure referred to in Article 42(3).
- 3a. *By ... [the date of application of this Regulation] the Commission shall develop an interoperable interface that allows providers of online marketplaces to link their interfaces to the Safety Gate Portal referred to in this Article.***
- 3b. *The Commission shall adopt implementing acts specifying the implementation of the interoperable interface on the Safety Gate Portal according to paragraph 3a, in particular concerning the access to the system and its operation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 42(3).***

Article 33

*Information from economic operators and providers of online marketplaces to consumers on product safety*

1. In case of a **product safety** recall, or where certain information has to be brought to the attention of consumers to ensure the safe use of a product ('safety warning'), economic operators, in accordance with their respective obligations as provided for in Articles 8, 9, 10 and 11, **and providers of online marketplaces in accordance with their obligations as provided for in Article 20 [(6)]**, shall **ensure that** all affected consumers that **can be identified are notified directly and without undue delay**. Economic operators **and, where applicable, providers of online marketplaces that** collect their customers' personal data shall make use of this information for recalls and safety warnings.
2. Where economic operators **and providers of online marketplaces have in place** product registration systems or customer loyalty programs **enabling the identification of products bought by consumers** for purposes other than contacting their customers with safety information, they shall offer the possibility to their customers to provide separate contact details only for safety purposes. The personal data collected for that purpose shall be limited to the necessary minimum and **shall** only be used to contact consumers in case of a recall or safety warning.

3. The Commission, by means of implementing acts, *may* set out, *for specific products or categories of products*, requirements *to be met by economic operators and providers of online marketplaces to provide the possibility for consumers to register a product they have purchased in order to be notified directly in case of product safety recalls or safety warnings in relation with this product, in accordance with paragraph 1*. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 42(3) ■
4. If not all affected consumers can be contacted *in accordance with paragraph 1*, economic operators *and providers of online marketplaces*, in accordance with their respective responsibilities, shall disseminate a *clear and visible* recall notice or safety warning through other appropriate channels, ensuring the widest possible reach including, where available: the company's website, social media channels, newsletters and retail outlets and, as appropriate, announcements in mass media and other communication channels. Information shall be accessible to consumers with disabilities.

#### *Article 34*

##### *Recall notice*

1. Where information on a recall is provided to consumers in a written form, in accordance with Articles 33(1) and (4), it shall take the form of a recall notice.
2. A recall notice *which can be easily understood by consumers* shall be available in the language(s) of the Member State(s) where the product has been put on the market and include the following elements:
  - (a) headline 'Product safety recall';
  - (b) clear description of the recalled product, including:
    - (i) *picture*, name and brand of the product;



- (ii) product identification numbers, such as batch or serial number, and, if applicable, graphical indication of where to find them on the product;
  - (iii) information on when, *where and by whom* the product was sold, if available.
- (c) clear description of the hazard associated with the recalled product, avoiding any elements that may decrease consumers' perception of risk, including terms and expressions such as "voluntary", "precautionary", "discretionary", "in rare/specific situations" as well as indicating that there have been no reported accidents;
  - (d) clear description of the action consumers should take, including an instruction to immediately stop using the recalled product;
  - (e) clear description of the *remedies* available to consumers *in accordance with Article 35*
  - (f) free phone number or interactive online service, where consumers can get more information in relevant official language(s) of the Union;
  - (g) an encouragement to further share information about the recall, if appropriate.
3. The Commission, by means of implementing acts, shall set out the template for a recall notice, taking into account scientific and market developments. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 42(2). *The template shall be made available by the Commission in a format that allows the easy creation of a recall notice by economic operators including in accessible formats.*

***Remedies in case of a product safety recall***

***1. Without prejudice to Directive (EU) 2019/770 and Directive (EU) 2019/771, in the case of a product safety recall initiated by an economic operator or ordered by a national competent authority the economic operator responsible for the recall shall offer to the consumer an effective, cost-free and timely remedy.***

***1a. Without prejudice to other remedies that may be offered by the economic operator, it shall offer to the consumer the choice between at least two of the following remedies:***

- (a) repair of the recalled product;***
- (b) replacement of the recalled product with a safe one of the same type and at least the same value and quality;***
- (c) adequate refund of the value of the recalled product, provided that the amount of the refund shall be at least equal to the price paid by the consumer.***

***Consumers may only be offered one remedy where the other remedies would be impossible or, compared to the proposed remedy, would impose costs on the economic operator that would be disproportionate, taking into account all circumstances, including whether the alternative remedy could be provided without significant inconvenience to the consumer.***

***The consumer shall always be entitled to a refund of the product when the economic operator responsible for the recall has not completed repair or replacement within a reasonable time without significant inconvenience for the consumer.***

2. Repair *by a consumer* shall only be considered an effective remedy where it can be carried out easily and safely by the consumer *in question when provided for in the recall notice*. In such cases, the economic operator responsible for the recall shall provide consumers with the necessary instructions **■** , free replacement parts or software updates. *Repair by a consumer shall not deprive the consumer of the rights provided for in Directive (EU) 2019/771 and Directive (EU) 2019/770*
- 2a. *Disposal of the product by consumers may only be included in the actions to be taken by consumers under Article 34(2)(d) where it can be carried out easily and safely by the consumer, and shall not affect the right of the consumer to receive a refund or replacement of the recalled product under paragraph 1.*
3. The remedy shall not entail significant inconvenience for the consumer. The consumer shall not bear the costs of shipping or otherwise returning the product. For products that by their nature are not portable, the economic operator shall arrange for the collection of the product.

### *Article 35a*

#### *Memoranda of understanding*

- 1. National competent authorities and the Commission may promote voluntary memoranda of understanding with economic operators or providers of online marketplaces, as well as with organisations representing consumers or economic operators, to undertake voluntary commitments with the aim of enhancing product safety.*
- 2. Voluntary commitments under such memoranda of understanding shall be without prejudice to the obligations of economic operators and providers of online marketplaces under this Regulation and other relevant Union legislation.*

### *Article 35b*

#### *Representative actions*

- 1. Directive (EU) 2020/1828 shall apply to the representative actions brought against infringements by economic operators and providers of online marketplaces of provisions of this Regulation that harm or may harm the collective interests of consumers.*

## CHAPTER IX

### International cooperation

#### Article 36

#### *International cooperation*

1. ***In order to improve the overall level of safety of consumer products made available on the Union market and to ensure a level playing field at international level, the Commission may cooperate, including through the exchange of information, with authorities of third countries or international organisations in the field of application of this Regulation, Any form of cooperation shall be based on reciprocity, include provisions on confidentiality corresponding to those applicable in the Union, and ensure that any exchange of information is in accordance with applicable Union law. The cooperation or exchange of information may relate, inter alia, to the following:***
  - (a) enforcement activities and measures related to safety, ***also with a view to preventing the circulation of dangerous products***, including market surveillance;
  - (b) risk assessment methods and product testing;
  - (c) coordinated product recalls and other similar actions;
  - (d) scientific, technical, and regulatory matters, aiming to improve product safety ***and to develop common priorities and approaches at international level***;
  - (e) emerging issues of significant health and safety relevance;
  - (ea) ***use of new technologies to improve product safety and increase traceability in the supply chain***;

- (f) standardisation-related activities;
  - (g) exchange of officials *and training programmes*.
2. The Commission may provide third countries or international organisations with selected information from *the* Safety Gate **Rapid Alert** system and receive relevant information on the safety of consumer products and on preventive, restrictive and corrective measures taken by those third countries or international organisations. The Commission shall share such information with national authorities, where relevant.
  3. The information exchange referred to in paragraph 2 may take the form of either:
    - (a) a non-systematic exchange, in duly justified and specific cases;
    - (b) a systematic exchange, based on an administrative arrangement specifying the type of information to be exchanged and the modalities for the exchange.
  4. Full participation in the Safety Gate **Rapid Alert** system may be open to applicant countries and third countries, provided that their legislation is aligned with the relevant Union legislation and that they participate in the European Standardisation System. Such participation shall entail the same obligations as for Member States according to this Regulation, including notification and follow-up obligations. Full participation in the Safety Gate **Rapid Alert System** shall be based on agreements between the Union and those countries, according to arrangements defined in these agreements.
  5. Any information exchange under this Article, to the extent it involves personal data, shall be carried out in accordance with Union data protection rules. Personal data shall only be transferred to the extent that such exchange is necessary for the sole purpose of the protection of consumers' health or safety.
  6. The information exchanged pursuant to this Article shall be used for the sole purpose of the protection of consumers' health or safety ■ .

## CHAPTER X

### Financial provisions

#### *Article 37*

#### *Financing activities*

1. The Union shall finance the following activities in relation to the application of this Regulation:
  - (a) performance of the tasks of the Consumer Safety Network referred to in Article 28;
  - (b) the development and operation of the Safety Gate **Rapid Alert System** referred to in Article 23, including the development of electronic interoperability solutions for:
    - the exchange of data between the Safety Gate **Rapid Alert System** and the national market surveillance systems;
    - the exchange of data between the Safety Gate **Rapid Alert System and** customs systems;
    - the exchange of data with other relevant restricted systems used by market surveillance authorities for their enforcement purposes.
  - (c) the development and maintenance of the Safety Gate portal referred to in Article 32 and the Safety Business Gateway, referred to in Article 25, including a public non-restricted software interface for data exchange with platforms and third parties.
2. The Union may finance the following activities in relation to the application of this Regulation:

- (a) the development of instruments of international cooperation referred to in Article 36;
- (b) the drawing up and updating of contributions to guidelines on market surveillance and product safety;
- (c) the making available to the Commission of technical or scientific expertise for the purpose of assisting the Commission in its implementation of market surveillance administrative cooperation;
- (d) the performance of preliminary or ancillary work in connection with the implementation of market surveillance activities linked to the application of this Regulation such as studies, programmes, evaluations, guidelines, comparative analyses, mutual joint visits and visit programmes, exchange of personnel, research work, the development and maintenance of databases, training activities, laboratory work, proficiency testing, inter-laboratory tests and conformity assessment work;
- (e) Union market surveillance campaigns and associated activities, including resources and equipment, IT tools and training;
- (f) activities carried out under programmes of technical assistance, cooperation with third countries and the promotion and enhancement of Union market surveillance policies and systems among interested parties at Union and international levels, ***including activities carried out by consumer organisations for the enhancement of consumer information.***



3. The Union's financial assistance to the activities under this Regulation shall be implemented in accordance with Regulation (EU, Euratom) No 2018/1046 of the European Parliament and of the Council<sup>19</sup>, either directly, or indirectly by delegating budget implementation tasks to the entities listed in Article 62(1), point (c) of that Regulation.
4. The appropriations allocated to activities referred to in this Regulation shall be determined each year by the budgetary authority within the limits of the financial framework in force.
5. The appropriations determined by the budgetary authority for the financing of market surveillance activities may also cover expenses pertaining to preparatory, monitoring, control, audit and evaluation activities which are required for the management of the activities pursuant to this Regulation and the achievement of their objectives; in particular, studies, meetings of experts, information and communication actions, including corporate communication of the political priorities of the Union as far as they are related to the general objectives of market surveillance activities, expenses linked to information technology networks focusing on information processing and exchange, together with all other technical and administrative assistance expenses incurred by the Commission for the management of the activities pursuant to this Regulation.

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<sup>19</sup> Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

*Article 38*

*Protection of the Union's financial interests*

1. The Commission shall take appropriate measures to ensure that, when actions financed under this Regulation are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportionate and dissuasive administrative and financial penalties.
2. The Commission or its representatives and the Court of Auditors shall have the power of audit, on the basis of documents and of on-the-spot inspections, over all grant beneficiaries, contractors and subcontractors who have received Union funds under the Single Market Programme and its successor<sup>20</sup> .
3. The European Anti-Fraud Office (OLAF) may carry out investigations, including on-the-spot checks and inspections, in accordance with the provisions and procedures laid down in Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council<sup>21</sup> and Council Regulation (Euratom, EC) No 2185/96<sup>22</sup>, with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with a grant agreement or grant decision or a contract funded under the programme.

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<sup>20</sup> OJ L292, 14.11.1996, p.2.

<sup>21</sup> Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1).

<sup>22</sup> Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

4. Without prejudice to paragraphs 1, 2 and 3, cooperation agreements with third countries and with international organisations, contracts, grant agreements and grant decisions resulting from the implementation of this Regulation shall contain provisions expressly empowering the Commission, the Court of Auditors and OLAF to conduct such audits and investigations, in accordance with their respective competences.

## CHAPTER XI

### Final provisions

#### *Article 39*

##### *Liability*

1. Any decision taken pursuant to this Regulation and involving restrictions on the placing of a product on the market or requiring its withdrawal or its recall shall not affect the assessment of the liability of the party concerned, in the light of the national law applying in the case in question.
2. This Regulation shall not affect Council Directive 85/374/EEC<sup>23</sup>.

#### *Article 40*

##### *Penalties*

1. ***The*** Member States shall lay down the rules on penalties applicable to infringements of this Regulation ***that impose obligations on economic operators and providers of online marketplaces and shall take all measures necessary to ensure that they are implemented in accordance with national law.***
2. ***The penalties provided for shall be effective, proportionate and dissuasive.***

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<sup>23</sup> Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 210, 7.8.1985, p. 29).

3. *The Member States shall, by [ 18 months after the date of entry into force of this Regulation], notify those provisions to the Commission, where they have not previously been notified, and shall notify it, without delay, of any subsequent amendment affecting them.*

2. █

3. █

4. █

5. █

6. █

7. █

8. █

*Article 41*  
*Exercise of the delegation*

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in **Articles 17(3) and 24(8)** shall be conferred on the Commission for an indeterminate period of time from [insert date - the date of entry into force of this Regulation].
3. The delegation of power referred to in Article 17(3) **and 24(8)** may be revoked at any time by the European Parliament or by the Council. A decision **to revoke** shall put an end to the delegation of the power specified in that decision. It shall take effect the day following **the publication of the decision** in the *Official Journal of the European Union* **■** or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016<sup>24</sup>.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

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<sup>24</sup> OJ L 123, 12.5.2016, p. 1

6. A delegated act adopted pursuant to *Articles 17(3) and 24(8)* shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of *three* months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period may be extended by two months at the initiative of the European Parliament or of the Council.

*Article 42*

*Committee procedure*

1. The Commission shall be assisted by a Committee. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

Article 43

*Evaluation and review*

1. By ... [insert date five years after the date of **application**] the Commission shall carry out an evaluation of this Regulation. The Commission shall present a report on the main findings to the European Parliament, the Council and the European Economic and Social Committee. The report shall **assess if this Regulation, and** in particular **Articles 17, 20 and 23**, achieved the objective of enhancing the protection of consumers against dangerous products while taking into account **the challenges posed by new technologies and** its impact on businesses and in particular on small and medium-sized enterprises.
  - 1a. **By ... [insert date five years after the date of application], the Commission shall carry out an evaluation report on the implementation of Article 15. That report shall in particular assess the scope, effects, and costs and benefits of that Article. The report shall be accompanied, where appropriate, by a legislative proposal.**
  - 1c. **By ... [three years after the date of application of this Regulation] the Commission shall assess the modalities for implementation of the provisions on the removal of illegal content from online marketplaces referred to in Article 20(2a) by means of a Union notification system designed and developed within the Safety Gate. The assessment shall be accompanied, where appropriate, by a legislative proposal.**
  - 1d. **By ... [two years after the date of application of this Regulation] the Commission shall present a report on the functioning of interconnection between Information and Communication system referred to in Article 34 of Regulation (EU) 2019/1020 and the Safety Gate referred to in this Regulation, including information on their respective functionalities, further improvements or on the development of a new interface, if appropriate.**



- 1e. ***By ... [insert date five years after the date of application], the Commission shall carry out an evaluation report on the implementation of Article 40. That report shall in particular assess the effectiveness and deterrent effect of the penalties imposed under that Article. The report shall be accompanied, where appropriate, by a legislative proposal."***
2. On request, Member States shall provide the Commission with information necessary for the evaluation of this Regulation.

*Article 44*

*Amendments to Regulation (EU) No 1025/2012*

1. Regulation (EU) No 1025/2012 is amended as follows:

In Article 10, the following paragraph 7 is added:

7. Where a European standard drafted in support of Regulation (EU) .../... of the European Parliament and of the Council<sup>1</sup>[*this Regulation*] satisfies the general safety requirement laid down in Article 5 of that Regulation and the specific safety requirements referred to in Article 6(2) of that Regulation, the Commission shall publish a reference of such European standard without delay in the *Official Journal of the European Union*.

In Article 11, paragraphs 1, 2 and 3 are replaced by the following:

1. When a Member State or the European Parliament considers that a harmonised standard or European standard drafted in support of Regulation (EU) .../... [*this Regulation*] does not entirely satisfy the requirements which it aims to cover and which are set out in the relevant Union harmonisation legislation or in that Regulation, it shall inform the Commission thereof with a detailed explanation. The Commission shall, after consulting the committee set up by the corresponding Union harmonisation legislation, if it exists, or the committee set up by Regulation (EU) .../... [*this Regulation* (*GPSR*)], or after other forms of consultation of sectoral experts, decide:
  - (a) to publish, not to publish or to publish with restriction the references to the harmonised standard or European standard drafted in support of Regulation (EU) .../... [*GPSR*] concerned in the *Official Journal of the European Union*;
  - (b) to maintain, to maintain with restriction or to withdraw the references to the harmonised standard or European standard drafted in support of Regulation (EU) .../... [*GPSR*] concerned in or from the *Official Journal of the European Union* .’
2. The Commission shall publish information on its website on the harmonised standards and European standards drafted in support of Regulation (EU) .../... [*GPSR*] that have been subject to the decision referred to in paragraph 1.
3. The Commission shall inform the European standardisation organisation concerned of the decision referred to in paragraph 1 and, if necessary, request the revision of the harmonised standards or of the European standards drafted in support of Regulation (EU) .../... [*GPSR*] concerned.’

*Article 44a*

*Amendments to Directive 2020/1828/EU*

1. *By [date of application of this Regulation] Annex I, point 8, of Directive 2020/1828/EU is replaced by the following:*

*"(8) Regulation (EU) [...] on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council, and repealing Council Directive 87/357/EEC and Directive 2001/95/EC of the European Parliament and of the Council (OJ L ..., ..., p. ...)."*

*Article 45*

*Repeal*

1. Directive 87/357/EEC and Directive 2001/95/EC are repealed with effect from [ **18 months after the** date of **entry into force of this Regulation**].
2. References to Directives 87/357/EEC and 2001/95/EC shall be construed as references to this Regulation and to Regulation (EU) No 1025/2012, and shall be read in accordance with the correlation table in the Annex.

*Article 46*  
*Transitional provisions*

Member States shall not impede the making available on the market of products covered by Directive 2001/95/EC which are in conformity with that Directive and which were placed on the market before [ **18 months after the** date of **entry into force of this Regulation** ].

*Article 47*  
*Entry into force and application*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [18 months after the entry into force of this Regulation].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*

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Correlation Table

Directive 87/357/EEC	Directive 2001/95/EC	Regulation (EU) No 1025/2012	This Regulation
	Article 1(2)		Article 2(1), (2)
	Article 2 except point (a) 2nd subparagraph and point (b) 2nd subparagraph		Article 3
	Article 2, point (a) 2nd subparagraph		Article 2(3)
	Article 2, point (b) 2nd subparagraph		Article 7(2)
	Article 3(1)		Article 5
	Article 3(2)		Article 6(1)
	Article 3(3)		Article 7(1)
	Article 3(4)		Article 6(3)
	Article 4(1), point (a)		Article 6(2)
	4(1), point (b)	Article 10(1)	
	4(1), point (c)	-	-
	4(1), point (d)	-	-
	Article 4(2), first subparagraph	Article 10(7)	

Directive 87/357/EEC	Directive 2001/95/EC	Regulation (EU) No 1025/2012	This Regulation
	Article 4(2), second subparagraph	-	-
	Article 4(2), third and fourth subparagraphs	Article 11(1)(b)	-
	Article 5(1), first subparagraph		Article 8(8)
	Article 5(1), second subparagraph		-
	Article 5(1), third subparagraph, point (a)		Article 8(2) first subparagraph, 10(6) third sentence
	Article 5(1), third subparagraph, point (b)		Article 8(11) and Article 10(8)
	Article 5(1), fourth subparagraph, point (a)		Article 8(6) and (7), Article 10(3)
	Article 5(1), fourth subparagraph, point (b) first sentence		Article 15(2) first sentence
	Article 5(1) forth subparagraph point (b) second sentence		Article 8(2) first subparagraph and Article 10(6)
	Article 5(1), fifth subparagraph		-
	Article 5(2)		Article 11(1) and (2)

Directive 87/357/EEC	Directive 2001/95/EC	Regulation (EU) No 1025/2012	This Regulation
	Article 5(3) first subparagraph		Article 8 (11), Article 10 (8) and Article 11 (4)
	Article 5(3) second subparagraph		-
	Article 5(4)		Article 14
	Articles 6 to 9		Article 21
	Article 10 (1)		Article 28
	Article 10(2)		Article 29
	Article 11(1), first subparagraph		Article 24(1)
	Article 11(1) second subparagraph		-
	Article 11(1) third subparagraph		Article 24(8)
	Article 11(2)		Article 24(3)
	Article 12(1), first and forth subparagraph		Article 24(1)
	Article 12(1), second subparagraph		-
	Article 12(1) third subparagraph		-
	Article 12(2)		Article 24(3)

Directive 87/357/EEC	Directive 2001/95/EC	Regulation (EU) No 1025/2012	This Regulation
	Article 12(3)		Article 24(8)
	Article 12(4)		Article 36(2),(3),(4),(5),(6)
	Article 13		Article 26
	Article 14		-
	Article 15		Article 42
	Article 16(1) first subparagraph		Article 31(1)
	Article 16(1) second subparagraph		Article 31(2)
	Article 16(2)		Article 31(3)
	Article 17		Article 39(2)
	Article 18(1) and (2)		Article 21
	Article 18(3)		Article 39(1)
	Article 19(1)		-
	Article 19(2)		Article 43
	Article 20		-
	Annex I (1)		Articles 8(11) and 10(8), 11(4) and (5)
	Annex I (2) and (3)		Article 26



Directive 87/357/EEC	Directive 2001/95/EC	Regulation (EU) No 1025/2012	This Regulation
	Annex III		-
	Annex IV		Annex
Article 1			-
Articles 2			Article 6(1) first subparagraph and 6(1)f
Articles 3 to 7			-

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