**EUROPEAN UNION**

**THE EUROPEAN PARLIAMENT** **THE COUNCIL**

**Brussels, 12 April 2023**
**(OR. en)**

**2021/0170(COD)** **PE-CONS 79/22**

**CONSOM 358**
**MI 983**
**COMPET 1074**
**DIGIT 253**
**CYBER 420**
**CHIMIE 109**
**JAI 1737**
**CODEC 2094**

**LEGISLATIVE ACTS AND OTHER INSTRUMENTS**

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| Subject: | 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 Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC |

**REGULATION (EU) 2023/...**
**OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**of ...**

**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 Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC**

**(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[1],

Acting in accordance with the ordinary legislative procedure[2],

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1 OJ C 105, 4.3.2022, p. 99.

2 Position of the European Parliament of 30 March 2023 (not yet published in the Official Journal) and decision of the Council of ….

Whereas:

(1) Directive 2001/95/EC of the European Parliament and of the Council[1] 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 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 Union harmonisation legislation and in standardisation legislation, to ensure a better functioning of product safety recalls as well as to ensure a clearer framework for food-imitating products hitherto regulated by Council Directive 87/357/EEC[2]. In the interest of clarity, Directives 2001/95/EC and 87/357/EEC should be repealed and replaced by this Regulation.

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1 Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4).

2 Council Directive 87/357/EEC of 25 June 1987 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).

(3) A regulation is the appropriate legal instrument as it imposes clear and detailed rules which leave no scope for divergent transposition by Member States. The choice of a regulation instead of a directive also allows for better delivery of the objective of ensuring coherence with the market surveillance legislative framework for products falling within the scope of Union harmonisation legislation, where the applicable legal instrument is also a regulation, namely Regulation (EU) 2019/1020 of the European Parliament and of the Council[1]. Finally, such a choice will further reduce the regulatory burden through a consistent application of product safety rules across the Union.

(4) The aim of this Regulation is to contribute to the attainment of the objectives referred to in Article 169 of the Treaty on the Functioning of the European Union (TFEU). In particular, it should aim to ensure the health and safety of consumers and the functioning of the internal market as regards products intended for consumers.

[1] 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).

(5) This Regulation should aim at protecting consumers and their safety as one of the fundamental principles of the Union legal framework and as enshrined in the Charter of Fundamental Rights of the European Union (the 'Charter'). Dangerous products can have very negative consequences for 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 should have adequate instruments and measures at their disposal to enforce this Regulation.

(6) Despite the development of sector-specific Union harmonisation legislation that addresses the safety aspects of specific products or categories of products, it is practically impossible to adopt Union law 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 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 the health and safety of consumers, as required by Articles 114 and 169 TFEU.

(7) At the same time, in respect of products that are subject to sector-specific Union harmonisation legislation, the scope of the different parts of this Regulation should be clearly set out to avoid overlapping provisions and to ensure a clear legal framework.

(8) Whilst some of the provisions of this Regulation, such as most of the obligations of economic operators, should not apply to products covered by Union harmonisation legislation, certain other provisions of this Regulation are complementary to Union harmonisation legislation and therefore should apply to such products. In particular, the general product safety requirement and related provisions should apply to consumer products covered by Union harmonisation legislation when certain types of risks are not covered by that Union harmonisation legislation. The provisions of this Regulation concerning the obligations of providers of online marketplaces, the obligations of economic operators in the event of accidents, the right to information and to a remedy for consumers as well as the product safety recalls should apply to products covered by Union harmonisation legislation to the extent that there are no specific provisions with the same objective in such Union harmonisation legislation. Likewise, RAPEX is already used for the purposes of Union harmonisation legislation, as referred to in Article 20 of Regulation (EU) 2019/1020: therefore the provisions of this Regulation regulating the Safety Gate and its functioning should apply to products covered by Union harmonisation legislation.

(9) 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.

(10) Medicinal products are subject to a pre-market assessment that includes a specific risk-benefit analysis. Those products should therefore be excluded from the scope of this Regulation.

(11) Union law on food, feed and related areas sets up a specific system ensuring the safety of the products covered by it. Indeed, food and feed products have a specific legal framework established, in particular, by Regulation (EC) No 178/2002 of the European Parliament and of the Council[1]. Furthermore, food and feed products are also regulated by Regulation (EU) 2017/625 of the European Parliament and of the Council[2], which ensures 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 products 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[3] or by other food-specific legislation which only covers chemical and biological food-related risks.

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1 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

2 Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

3 Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 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).

(12) Living plants are subject to a specific legal framework, provided for, in particular, by Regulation (EU) 2016/2031 of the European Parliament and of the Council[1] which takes into consideration the specificities of those products to ensure consumer safety.

(13) Animal by-products are materials of animal origin that people do not consume. Those products, such as feed, are subject to a specific legal framework, provided for, in particular, by Regulation (EC) No 1069/2009 of the European Parliament and of the Council[2].

(14) Plant protection products, also referred to as pesticides, are subject to specific provisions for their authorisation at national level, based on Regulation (EC) No 1107/2009 of the European Parliament and of the Council[3], and should therefore also be excluded from the scope of this Regulation.

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1 Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).

2 Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

3 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

(15) Aircraft referred to in Article 2(3), point (d) of Regulation (EU) 2018/1139 of the European Parliament and of the Council[1] are subject to the regulatory control of the Member States, in light of their limited risk to civil aviation safety. Those aircraft 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 on the market as collectible items of historical significance.

[1] 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).

(17) Services should not be covered by this Regulation. However, in order to protect the 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 the provision of a service, should fall within the scope of this Regulation. However, equipment on which consumers ride or travel, where such equipment 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.

(18) Antiques, such as works of art or collectors' items are specific categories of products which cannot be expected to meet the safety requirements laid down by this Regulation, and should therefore be excluded from its scope. However, in order to prevent other products from being mistakenly considered as belonging to those categories, it is necessary to take into account that works of art are products created solely for artistic purposes, that collectors' items are of sufficient rarity and historical or scientific interest to justify their collection and preservation, and that antiques, if they are not already works of art or collectors' items or both, are of an extraordinary age. When assessing whether a product is an antique, such as a work of art or a collector's item, Annex IX to Council Directive 2006/112/EC[1] could be taken into account.

[1] Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax (OJ L 347 11.12.2006, p. 1).

(19) 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.

(20) 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 providers of online marketplaces.

(21) 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 should 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.

(22) Under the general safety requirement laid down in this Regulation, economic operators should be obliged to place only safe products on the market. Such a high level of safety should be primarily achieved through the 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 by means of certain safeguards, such as warnings and instructions.

(23) The safety of a product should be assessed taking into account all relevant aspects of the product, in particular its characteristics, such as the physical, mechanical and chemical characteristics, and its presentation, as well as the specific needs and risks which the product represents for certain categories of consumers who are likely to use the products, in particular children, older persons and persons with disabilities. Those risks can also include environmental risk insofar as it poses a risk to the health and safety of consumers. That assessment should take into account the health risk posed by digitally connected products, including the risk to mental health, especially of vulnerable consumers, in particular children. Therefore, when assessing the safety of digitally 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 for a certain category of persons, the assessment of the safety of the products should take into consideration also the presence of that 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) 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 given due consideration as a potential risk. The connections and interrelation that an item might have with external items should not jeopardise its safety.

(25) New technologies might 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 might substantially modify the original product, for instance through software updates, which should then be subject to a new risk assessment if that substantial modification were to have an impact on the safety of the product.

(26) Specific cybersecurity risks affecting the safety of consumers, as well as protocols and certifications, can be dealt with by sectoral legislation. However, it should be ensured that, in cases where such sectoral legislation does not apply, the relevant economic operators and national authorities take into consideration risks linked to new technologies, when designing the products and assessing them respectively, in order to ensure that changes introduced in the product do not jeopardise its safety.

(27) In order to facilitate the effective and consistent application of the general safety requirement laid down 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 laid down in this Regulation. Standardisation requests issued by the Commission in accordance with Directive 2001/95/EC should be deemed to be standardisation requests issued in accordance with this Regulation. In the event that 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 a presumption of safety as far as the relevant risk or risk category is concerned.

(28) Where the Commission identifies a need for a European standard ensuring compliance of certain products with the general safety requirement laid down in this Regulation, it should apply the relevant provisions of Regulation (EU) No 1025/2012 of the European Parliament and of the Council[1] to request one or more 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.

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[1] 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).

(29) Products could present different risks for different genders and standardisation activities should take that into account to avoid discrepancies in terms of safety and therefore a gender safety gap. The Declaration on Gender Responsive Standards of the United Nations Economic Commission for Europe 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.

(30) Together with the adaptation of Regulation (EU) No 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.

(31) In the absence of European standards, the national 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 TFEU.

(32) 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 the 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, as regards the verification of whether the manufacturer and, where relevant, the importer have complied with their obligations, the distributor 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 and of the economic operators, as well as instructions and safety information, could in addition be provided by the economic operators in a digital form by means of electronic solutions, such as a QR or data matrix code.

(33) Manufacturers should draw up technical documentation regarding the products they place on the market, which should contain the necessary information to prove that those 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 the 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, an analysis of those risks and the technical means adopted to mitigate or eliminate the risks should also be included. Where the product complies with European standards or other elements applied to meet the general safety requirement laid down in this Regulation, the list of the relevant European standards or the other elements should also be indicated.

(34) 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 might be affected, should be considered to be the manufacturer and should assume the obligations of the manufacturer.

(35) Modification of a product, by physical or digital means, 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 which might jeopardise the safety of the product. Such modification should therefore be considered as a substantial modification and, when not done by the consumer or on his behalf, should lead to the product being considered as a new product from a different manufacturer. In order to ensure compliance with the general safety requirement laid down in this Regulation, the person that carries out that 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 that carries out the substantial modification to demonstrate that the modification does not have an impact on the product as a whole.

(36) Internal conformity procedures, through which economic operators ensure, internally, the effective and swift performance of their obligations as well as the conditions to react timely in the case of a dangerous product, should be put in place by the economic operators themselves.

(37) In order to prevent the placing on the market of dangerous products, it should be compulsory for economic operators to include in their production or marketing activities internal processes ensuring compliance with the relevant requirements of this Regulation. Such internal processes should be determined by economic operators themselves in relation to their role in the supply chain and the type of products concerned and can be based, for example, upon organisational procedures, guidelines, standards or upon the appointment of an ad hoc manager. The establishment and format of such internal processes should remain the sole responsibility of relevant economic operators.

(38) 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 regard to their respective legal obligations.

(39) 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 neither 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 tackle in an effective manner the sale of dangerous products online. In order to ensure the effective enforcement of this Regulation, the obligation set out in Article 4(1), (2) and (3) of Regulation (EU) 2019/1020 should be extended to products falling outside the scope of 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 compliance with the technical documentation, product and manufacturer information, instruction and safety information.

(40) The contact information of the economic operator established in the Union and responsible for products falling within the scope of this Regulation should be indicated with the product in order to facilitate checks throughout the supply chain.

(41) In order for economic operators that are small and medium-sized enterprises (SMEs), including micro-enterprises, 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 the event of questions, taking into account the need to simplify and limit their administrative burdens.

(42) Ensuring product identification and the provision of 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 the provision of 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, where applicable, of the importer and other relevant economic operators. Such requirements could be made stricter for certain kinds of products that are likely to present a serious risk to the 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 of the European Parliament and of the Council[1], related to the main characteristics of the goods, to the extent appropriate to the medium and to the nature of 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.

[1] 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).

(43) 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 law and such notification and collection of data should not therefore be considered as an admission of liability for a defective product or as confirmation of liability under relevant Union or national law.

(44) 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.

(45) Providers of online marketplaces play a crucial role in the supply chain, allowing economic operators to reach a greater number of consumers, and therefore also in the product safety system.

(46) 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 can fall within different categories of business models under this Regulation. When an entity provides only online intermediation services for a given product, then it would qualify only as a provider of an online marketplace for that product. In the event that the same entity provides both online marketplace services for the sale of a particular product and also acts as an economic operator under 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 the obligations applicable to the relevant economic operator. 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.

(47) 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[1] provides the general framework for e-commerce and lays down certain obligations for online platforms.
Regulation (EU) 2022/2065 of the European Parliament and of the Council[2] 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 tackle in an effective manner 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 are to comply in order to ensure compliance with certain provisions of Regulation (EU) 2022/2065, those requirements should not affect the application of Regulation (EU) 2022/2065, which continues to apply to those providers of online marketplaces.

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1 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).

2 Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act) (OJ L 277, 27.10.2022, p. 1).

(48) The Product Safety Pledge, first signed in 2018 and joined by a number of providers of online 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 undertake 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 the Safety Gate Portal, can allow the automatic identification and communication of notified dangerous products and to carry out automated random checks against the Safety Gate Portal.

(49) Providers of online marketplaces should act with due care in relation to the content hosted on their online interfaces that concerns product safety, in accordance with the specific obligations laid down in this Regulation. Accordingly, this Regulation should lay down due diligence obligations for all providers of online marketplaces in relation to the content hosted on their online interfaces that concerns product safety.

(50) Moreover, for the purposes of effective market surveillance, providers of online marketplaces should register in the Safety Gate Portal and indicate, in the Safety Gate Portal, the information concerning their single point of contact 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) 2022/2065, without endangering the objective of treating issues linked to product safety in a swift and specific manner.

(51) Providers of online marketplaces should designate a single point of contact for consumers. That single point of contact should serve as a single window for consumer communications on product safety issues, which can 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) 2022/2065.

(52) In order to be able to comply with their obligations under this Regulation, in particular in respect of the timely and effective compliance with the orders of public authorities, the processing of notices of other third parties and cooperation 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.

(53) 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, those powers 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 should introduce binding time-limits in that respect. Those powers should be exercised in accordance with Article 9 of Regulation (EU) 2022/2065.

(54) 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 an online marketplace to remove identical offers, based on the information displayed by the traders, to the extent that the provider of an online marketplace is not required to carry out an independent assessment of that content.

(55) 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 a dangerous product, 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 online interface, 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 of this Regulation on the removal of content referring to an offer of a dangerous product from online interfaces by means of a notification system designed and developed within the Safety Gate Portal.

(56) The obligations imposed by this Regulation on providers of online marketplaces should not amount to a general obligation to monitor the information which they transmit or store, nor should they require providers of online marketplaces to actively seek facts or circumstances indicating illegal activity, such as the sale of dangerous products online. Nonetheless, in order to benefit from the exemption from liability for hosting services under Directive 2000/31/EC and Regulation (EU) 2022/2065, providers of online marketplaces should remove content referring to an offer of a dangerous product from their online interfaces expeditiously, upon obtaining actual knowledge or, in the case of claims for damages, upon becoming aware of the content referring to an offer of a dangerous product, in particular in cases in which 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. Providers of online marketplaces should process notices concerning content referring to an offer of a dangerous product, received in accordance with Article 16 of Regulation (EU) 2022/2065, 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.

(57) For the purposes of Article 22 of Regulation (EU) 2022/2065, and concerning the safety of products sold online, the Digital Services Coordinator should consider in particular consumer organisations and associations representing consumers' interests and other relevant stakeholders, upon their request, as trusted flaggers, provided that the conditions set out in that Article have been met.

(58) 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) 2022/2065 concerning the traceability of traders, providers of online marketplaces should not allow a specific product offer to be listed on their platforms unless the trader has provided all information related to product safety and traceability as specified 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, providers of online marketplaces 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 lies with the relevant trader.

(59) It is also important that providers of online marketplaces cooperate closely with the market surveillance authorities, with traders and with relevant economic operators on the safety of products. Article 7(2) of Regulation (EU) 2019/1020 imposes an obligation on information society service providers to cooperate with market surveillance authorities in relation to products covered by that Regulation. That obligation should therefore be extended to all consumer products. For instance, market surveillance authorities are constantly improving the technological tools they use for online market surveillance to identify dangerous products sold online. For those tools to be operational, providers of online marketplaces should grant access to their interfaces. Moreover, for the purpose of product safety, market surveillance authorities should also have the possibility to scrape data from an online interface upon reasoned request in the 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.

(60) 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 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 should apply also to products covered by this Regulation.

(61) Pursuant to Regulation (EU) No 952/2013 of the European Parliament and of the Council[1] (the Union Customs Code), 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'. That procedure aims to complete the formalities laid down in respect of the import of the goods, including the enforcement of the applicable provisions of Union law, so that those goods can be made available on the Union market like any product made in the Union. As far as consumer safety is concerned, those products are required to comply with this Regulation and, in particular, with the general safety requirement laid down in this Regulation.

(62) Chapter VII of Regulation (EU) 2019/1020, laying down rules for controls on products entering the Union market, is already directly applicable to products covered by this Regulation. The authorities in charge of those 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 implementing legislation and corresponding guidance. Therefore, this Regulation does not modify in any way Chapter VII of Regulation (EU) 2019/1020 and the way the authorities in charge of controls on products entering the Union market organise themselves and perform their activities.

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[1] Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269 10.10.2013, p. 1).

(63) Member States should ensure that any measures taken by their competent authorities under this Regulation are subject to effective judicial remedies in accordance with Article 47 of the Charter.

(64) 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.

(65) Member States should also ensure that the market surveillance authorities have sufficient expertise and resources for all their enforcement activities.

(66) 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 measurement of the effectiveness of Union product safety legislation.

(67) 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 thereby to protect the health and safety of consumers.

(68) 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 to change the 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, a web portal to enable businesses to comply with their obligation to inform authorities and consumers of dangerous products and accidents (Safety Business Gateway). Interfaces should 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 which can 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 entered 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.

(69) 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 the case of products covered by Regulation (EU) 2019/1020, also to other relevant public interests of end-users.

(70) Under Article 34 of Regulation (EU) 2019/1020, Member States' authorities are to notify measures taken against products covered by that Regulation, presenting a less than serious risk, through the information and communication system referred to in that Article, while corrective measures taken 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 risks to the health and safety of consumers posed by products. It is opportune for consumers and businesses that all information on corrective measures taken against products presenting a serious risk is 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 a clear and understandable manner. Member States are therefore encouraged to notify in the Safety Gate Rapid Alert System all corrective measures on products presenting a risk to the health and safety of consumers.

(71) In the event that the information has to be notified in the information and communication system in accordance with 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 that purpose, the Commission should maintain and further develop the interface that has been set up for the transfer of information between that information and communication system and the Safety Gate Rapid Alert System, in order to avoid double data entry and to facilitate such transfer.

(72) 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.

(73) There might be cases where it is necessary to deal with a serious risk at 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 law. This could in particular be the case as regards new emerging risks or those impacting vulnerable consumers. For that reason the Commission should be able to 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.

(74) 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 such a 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 internal 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.

(75) The Commission should draw up a periodic report on the application of the mechanism under Article 29, which should be presented to the European network of the Member States' authorities competent for product safety under this Regulation ('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.

(76) 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 and the exchange of expertise and best practices. It should also contribute to the harmonisation of the methodologies to collect data on product safety, as well as to an increase in the interoperability between regional, sectoral, 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 within the scope of both Regulations is necessary to ensure their effectiveness.

(77) To preserve the coherence of the market surveillance legal framework and, at the same time, ensure an effective cooperation between the Consumer Safety Network 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.

(78) Market surveillance authorities should carry out joint activities with other authorities or organisations representing economic operators or consumers, with a view to promoting the 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.

(79) 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.

(80) Simultaneous coordinated control actions (‘sweeps’) are specific enforcement actions that could further enhance product safety and should therefore 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.

(81) 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 TFEU, should be protected in a way which is compatible with the need to ensure the effectiveness of market surveillance activities and of protection measures.

(82) Complaints are important in terms of raising awareness of national authorities about the safety and effectiveness of surveillance and control activities relating to dangerous products. Member States should therefore give to consumers and other interested parties such as consumer associations and economic operators the possibility to submit such complaints.

(83) 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 found on the market presenting a risk to the health and safety of consumers. Where relevant, the Commission should provide adequate follow-up, in particular by transmitting such information to the national authorities concerned. The database and website of the Safety Gate should be easily accessible for persons with disabilities.

(84) After verification of the accuracy of the information received from consumers and other interested parties, the Commission should ensure an appropriate follow-up. In particular, the Commission 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.

(85) 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 the 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 that respect, economic operators and providers of online marketplaces should ensure that they 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 at 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.

(86) 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 that product. In determining the specific products or categories of products subject to that 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.

(87) One-third of consumers continue to use dangerous products despite seeing a recall notice, particularly 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 the risk. Consumers should also be able to get more information, if needed, through a toll-free telephone number or other interactive instrument.

(88) 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[1] provides 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[2] 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 of remedying the lack of conformity of the goods with the contract, the remedies in the event 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 the event of a product recall under this Regulation, there should be no time limitation to activate the remedies; secondly, the consumer should be entitled to request remedies from the relevant economic operator, not necessarily from the trader. Moreover, in the event of a recall, the consumer should not have to prove that the product is dangerous.

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1 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).

2 Directive (EU) 2019/770 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the supply of digital content and digital services (OJ L 136, 22.5.2019, p. 1).

(89) Given the different objectives of remedies provided in the event 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 a 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.

(90) Once the consumer has been provided with a remedy as a follow-up to 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 the event that the consumer invokes the consumer's rights to a remedy under Directive (EU) 2019/770 or Directive (EU) 2019/771, 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.

(91) 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 the event of recalls of the tangible medium for digital content within the meaning of Article 2, point (1) of Directive (EU) 2019/770, the refund should cover all sums paid by the consumer under the contract, as provided for in Article 16(1) of that Directive. Any remedy should be without prejudice to the consumers' right to damages under national law.

(92) Remedies offered in the event 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 Directives (EU) 2019/770 and (EU) 2019/771. Therefore, in such situations, economic operators should not oblige consumers to repair a dangerous product.

(93) This Regulation should also encourage 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.

(94) 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[1]. For that purpose, this Regulation should provide that Directive (EU) 2020/1828 is applicable to the representative actions concerning infringements of this Regulation that harm or can harm the collective interests of consumers. Annex I 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 that Directive, although the adoption of national transposition measures in that regard is not a condition for the applicability of that Directive to those representative actions. The applicability of that Directive 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 to that Directive.

[1] Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC (OJ L 409, 4.12.2020, p. 1).

(95) 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 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 the health or safety of consumers.

(96) 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 third country producing goods destined for the Union market might consist in the Commission sending selected information from the Safety Gate Rapid Alert System related to products originating from that third country. In exchange, that 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.

(97) In order to have 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 provider of an online marketplace and to the type and gravity of the injury suffered by the consumer. Penalties should be effective, proportionate and dissuasive.

(98) When imposing penalties, due consideration 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.

(99) In order to maintain a high level of health and safety of consumers, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the identification and traceability of products bearing a potential serious risk to the health and safety of consumers 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 carry 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[1]. 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.

[1] OJ L 123, 12.5.2016, p. 1.

(100) 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 specify tasks and roles of single national contact points; 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 specify the implementation of the interoperable interface on the Safety Gate Portal; to set out the requirements for registration of products for product safety 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[1].

(101) 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.

(102) The Commission should carry out an evaluation of the implementation of the penalties laid down under this Regulation as regards their effectiveness and deterrent effects, and, where appropriate, adopt a legislative proposal in relation to their enforcement.

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[1] 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).

(103) Certain provisions of Regulation (EU) No 1025/2012 should be amended to take the specificities of this Regulation into account, and in particular the need to determine the specific safety requirements under this Regulation before launching the request to the European standardisation organisation.

(104) Directive 87/357/EEC, which covers consumer products which, although not foodstuff, resemble foodstuff and are likely to be confused with foodstuff in such 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, that Directive was adopted at a time where the legal framework for consumer product safety was very limited in scope. For those reasons, Directive 87/357/EEC should be repealed and replaced by this Regulation, in particular, the provisions of this Regulation which ensure that, following risk assessment, products 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, inter alia, 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 should assess on a case-by-case basis whether such products are dangerous and justify that assessment.

(105) 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 date of 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.

(106) Since the objective of this Regulation, namely to improve the functioning of the internal market while providing for a high level of consumer protection, 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 that objective.

(107) 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 Regulations (EU) 2016/679[1] and (EU) 2018/1725[2] and Directive 2002/58/EC[3] of the European Parliament and of the Council, as applicable. When consumers report a product in the Safety Gate Portal, only those personal data should be stored that are necessary to report the dangerous product and for a period not exceeding five years after such data have been entered. 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.

(108) The European Data Protection Supervisor was consulted in accordance with Article 42 of Regulation (EU) 2018/1725,

HAVE ADOPTED THIS REGULATION:

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1 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

2 Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

3 Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) (OJ L 201, 31.7.2002, p. 37).

# Chapter I
# General provisions

*Article 1*

*Objective and 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 applies to products that are placed or made available on the market insofar as there are no specific provisions with the same objective under Union law which regulate the safety of the products concerned.

   Where products are subject to specific safety requirements imposed by Union law, this Regulation applies only to those aspects and risks or categories of risks which are not covered by those requirements.

With regard to products subject to specific requirements imposed by Union harmonisation legislation as defined in Article 3, point (27):

(a) Chapter II does 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 and Chapters IX to XI do not apply.

2. This Regulation does 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 where that equipment is directly operated by a service provider within the context of a transport service provided to consumers and is not operated by the consumers themselves;

(h) aircraft referred to in Article 2(3), point (d) of Regulation (EU) 2018/1139;

(i) antiques.

3. This Regulation applies to products placed or made available on the market whether new, used, repaired or reconditioned. It does not apply to products to be repaired or reconditioned prior to being used where those products are placed or made available on the market and are 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, whether or not it is interconnected to other items, supplied or made available, whether for consideration or not, including in the context of providing a service, which is intended for consumers or is likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them;

(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 the health and safety of consumers;

(3) ‘dangerous product’ means any product which is not a ‘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 that person’s 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 that manufacturer’s 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[1], parcel delivery services as defined in Article 2, point (2) of Regulation (EU) 2018/644 of the European Parliament and of the Council[2], 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 or making them available on the market in accordance with this Regulation;

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1 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).

2 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).

(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;

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

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

(18) ‘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 that natural or legal person’s name or on that natural or legal person’s behalf, for purposes relating to the natural or legal person’s trade, business, craft or profession;

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

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

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

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

(23) ‘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;

(24) ‘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;

(25) ‘recall’ means any measure aimed at achieving the return of a product that has already been made available to the consumer;

(26) ‘withdrawal’ means any measure aimed at preventing a product in the supply chain from being made available on the market;

(27) ‘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;

(28) ‘antiques’ means products, such as collectors’ items or works of art, in relation to which consumers cannot reasonably expect that they fulfil state-of-the-art safety standards.

*Article 4*

*Distance sales*

Products offered for sale online or through other means of distance sales shall be deemed to be made available on the market if the offer is targeted at consumers in the Union. An offer for sale shall be considered to be targeted at consumers in the Union if the relevant economic operator directs, by any means, its activities to one or more Member States.

# Chapter II
# Safety requirements

*Article 5*

*General safety requirement*

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

*Article 6*

*Aspects for assessing the safety of products*

1. When assessing whether a product is a safe product, the following aspects in particular shall be taken 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 the product will be used with other products, including the interconnection of those products;

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

(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 lead consumers to use the product in a way different to 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 might therefore be placed in the mouth, sucked or ingested by consumers, especially by children;

(ii) where a product, although neither designed nor intended for use by children, is likely to be used by children or resembles an object commonly recognised as appealing to or intended for use by children because of its design, packaging or characteristics;

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

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

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 to be a dangerous product.

*Article 7*

*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 of this Regulation in the following cases:

   (a) 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 any European standards as referred to in point (a) of this paragraph, the product conforms to national requirements, as regards the risks and risk categories covered by health and safety requirements laid down in the national law of the Member State in which 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 those 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 46(3).

3. However, the 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 8*

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

1. For the purpose of Article 6 and where the presumption of safety under Article 7 does not apply, when assessing whether a product is safe, the following elements in particular shall be taken 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) No 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 law;

(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 recognised 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 7(2).

# Chapter III
# Obligations of economic operators

## SECTION 1

*Article 9*

*Obligations of manufacturers*

1. When placing their products on the market, manufacturers shall ensure that those products have been designed and manufactured in accordance with the general safety requirement laid down in Article 5.

2. Before placing their products on the market, manufacturers shall carry out an internal risk analysis and draw up technical documentation containing at least a general description of the product and its essential characteristics 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) 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; and

(b) the list of any relevant European standards as referred to in Article 7(1), point (a), or the other elements referred to in Article 7(1), point *(*b) or Article *8*, applied to meet the general safety requirement laid down in Article 5.

Where any of the European standards, health and safety requirements or elements as referred to in Article 7(1) or Article 8 have been only partly applied, the manufacturers shall identify the parts which have been applied.

3. Manufacturers shall ensure that the technical documentation referred to in paragraph 2 is up to date. They shall keep that documentation at the disposal of the market surveillance authorities for a period of ten years after the product has been placed on the market and make that documentation available to those authorities upon request.

4. 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.

5. Manufacturers shall ensure that their products bear a type, batch or serial number or other element enabling the identification of the product and 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.

6. 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. That information shall be placed on the product or, where that is not possible, on its packaging or in a document accompanying the product.

7. 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 on the market. That requirement shall not apply where the product can be used safely and as intended by the manufacturer without such instructions and safety information.

8. Where a manufacturer considers or has reason to believe, on the basis of the information in that manufacturer's possession, that a product which it has placed on the market is a dangerous product, the manufacturer shall immediately:

   (a) take the corrective measures necessary to bring in an effective manner the product into conformity, including a withdrawal or recall, as appropriate;

   (b) inform consumers thereof, in accordance with Article 35 or 36, or both; and

   (c) inform, through the Safety Business Gateway, the market surveillance authorities of the Member States in which the product has been made available on the market thereof.

For the purposes of points (b) and (c) of the first subparagraph, the manufacturer shall give details, in particular, of the risk to the 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 on the market.

9. The Commission shall ensure that the information meant to alert consumers can be provided by manufacturers through the Safety Business Gateway and is made available to consumers on the Safety Gate Portal without undue delay.

10. Manufacturers shall ensure that other economic operators, responsible persons, and providers of online marketplaces in the supply chain concerned are kept informed in a timely manner of any safety issue that they have identified.

11. 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, enabling consumers to submit complaints and to inform manufacturers of any accident or safety issue they have experienced with a product.

12. Manufacturers shall investigate complaints submitted, and information received on accidents, that concern the safety of products they made available on the market and which have been alleged to be 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.

13. The internal register of complaints shall only store 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 is necessary for the purposes of the investigation and in any event no longer than five years after the data have been entered.

*Article 10*

*Obligations of authorised representatives*

1. A manufacturer may, by means of a written mandate, appoint an authorised representative.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The authorised representative shall provide the market surveillance authorities with a copy of that mandate upon request. The mandate shall allow the authorised representative to perform at least the following tasks:

   (a) providing a market surveillance authority, upon that authority's 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 considers or has reason to believe that a product in question is a dangerous product, informing the manufacturer thereof;

(c) 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, where the information has not been already provided by the manufacturer or upon instruction of the manufacturer;

(d) cooperating with the competent national authorities, at their request, on any action taken to eliminate in an effective manner the risks posed by products covered by their mandate.

*Article 11*

*Obligations of importers*

1. Before placing a product on the market, importers shall ensure that the product complies with the general safety requirement laid down in Article 5 and that the manufacturer has complied with the requirements set out in Article 9(2), (5) and (6).

2. Where an importer considers or has reason to believe, on the basis of the information in that importer's possession, that a product is not in conformity with Article 5 and Article 9(2), (5) and (6), the importer shall not place the product on the market until the product has been brought into conformity. Furthermore, where the product is a dangerous product, the importer shall immediately inform the manufacturer thereof and ensure that the market surveillance authorities are informed thereof through the Safety Business Gateway.

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. That information shall be placed on the product or, where that is not possible, on its packaging or in a document accompanying the product. Importers shall ensure that any additional label does not obscure any information required by Union law 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 on the market, 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 jeopardise its conformity with the general safety requirement laid down in Article 5 and its conformity with Article 9(5) and (6).

6. Importers shall keep the copy of technical documentation referred to in Article 9(2) at the disposal of the market surveillance authorities for a period of 10 years after they have placed the product on the market and shall ensure that the documents referred to in Article 9(2), as applicable, can be made available to those authorities, upon request.

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

8. Where an importer considers or has reason to believe, on the basis of the information in that importer's possession, that a product which it has placed on the market is a dangerous product, the importer shall immediately:

(a) inform the manufacturer thereof;

(b) ensure that the corrective measures necessary to bring in an effective manner the product into conformity are taken including withdrawal or recall, as appropriate; where such measures have not been taken, the importer shall immediately take them;

(c) ensure that consumers are immediately informed thereof in accordance with Article 35 or 36, or both; and

(d) inform the market surveillance authorities of the Member States in which the product has been made available on the market thereof, through the Safety Business Gateway.

For the purposes of points (c) and (d) of the first subparagraph the importer 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 on the market.

9. Importers shall verify whether the communication channels referred to in Article 9(11) are publicly available to consumers, thereby allowing them to present complaints and communicate any accident or safety issue they have experienced with the product. If such channels are not available, importers shall provide for them, taking into account accessibility needs for persons with disabilities.

10. Importers shall investigate complaints submitted, and information received on accidents, that concern the safety of products they made available on the market, which the complainant has alleged to be dangerous, and file those complaints, as well as product recalls and any corrective measures taken to bring the product into conformity, in the register referred to in Article 9(12), 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.

11. The register of complaints shall only store those personal data that are necessary for the importer to investigate the complaint about an alleged dangerous product. Such data shall only be kept for as long as is necessary for the purposes of the investigation and in any event no longer than five years after the data have been entered.

*Article 12*

*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 9(5), (6) and (7) and Article 11(3) and (4), as applicable.

2. Distributors shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its conformity with the general safety requirement laid down in Article 5 and its conformity with Article 9(5), (6) and (7) and Article 11(3) and (4), as applicable.

3. Where a distributor considers or has reason to believe, on the basis of the information in that distributor's possession, that a product is not in conformity with Article 5, Article 9(5), (6) and (7), and Article 11(3) and (4), as applicable, the distributor shall not make the product available on the market unless the product has been brought into conformity.

4. Where a distributor considers or has reason to believe, on the basis of the information in that distributor's possession, that a product which it has made available on the market is a dangerous product or is not in conformity with Article 9(5), (6) and (7) and Article 11(3) and (4), as applicable, the distributor shall:

(a) immediately inform the manufacturer or the importer, as applicable, thereof;

(b) ensure that the corrective measures necessary to bring in an effective manner the product into conformity are taken, including withdrawal or recall, as appropriate; and

(c) ensure that the market surveillance authorities of the Member States in which the product has been made available on the market are immediately informed thereof through the Safety Business Gateway.

For the purposes of points (b) and (c) of the first subparagraph the distributor shall give appropriate details available to it of the risk to health and safety of consumers, of the number of products involved and of any corrective measure already taken.

*Article 13*

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

1. A natural or legal person shall be deemed to be a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 9 where that natural or legal person places a product on the market under the natural or legal person's name or trademark.

2. A natural or legal person, other than the manufacturer, that substantially modifies the product, shall be deemed to be a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 9 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.

3. 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 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; and

(c) the modifications have not been made by the consumers themselves or on their behalf for their own use.

*Article 14*

*Internal processes for product safety*

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 15*

*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 products which they made available on the market.

2. On request by a market surveillance authority, the economic operator shall provide all necessary information, in particular:

(a) a full description of the risk presented by the product, related complaints and known accidents; and

(b) a description of any corrective measure taken 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; and

(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 or after they have supplied the product, as applicable.

5. 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, or with a part, a component or any software embedded into the product, or after they have supplied the product, as applicable.

6. 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 16*

*Responsible person for products placed on the Union market*

1. A product covered by this Regulation shall not be placed on the market unless 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 that Regulation 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 that Regulation 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 of this Article shall regularly check:

(a) that the product complies with the technical documentation referred to in Article 9(2) of this Regulation;

(b) that the product complies with the requirements provided for in Article 9(5), (6) and (7) of this Regulation.

The economic operator referred to in paragraph 1 of this Article shall, upon request by the market surveillance authorities, provide 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 17*

*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 of the European Parliament and of the Council[1] 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.

[1] Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008 (OJ L 91, 29.3.2019, p. 1).

*Article 18*

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

1. For certain products, categories or groups of products which are likely to present a serious risk to the 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, relevant expert groups and relevant stakeholders, the Commission may set up a system of traceability to which economic operators who place and make available those products on the market shall adhere.

2. The system of traceability shall consist of 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 45 to supplement this Regulation by:

(a) determining the products, categories or groups of products or components likely to present a serious risk to the health and safety of consumers as referred to in paragraph 1; the Commission shall state in the delegated acts concerned whether it has used the risk analysis methodology provided for in Commission Implementing Decision (EU) 2019/417[1] 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 are to collect and store by means of the system of traceability 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 as 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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[1] 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).

4. Market surveillance authorities, consumers, economic operators and other relevant actors shall have access free of charge 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).

5. When adopting the measures referred to in paragraph 3, the Commission shall take into account:

(a) the cost-effectiveness of the measures, including the impact of the measures on businesses, in particular SMEs;

(b) an adequate timeframe to allow economic operators to prepare for those measures; and

(c) the compatibility and interoperability with other product traceability systems already set up at Union or at international level.

## SECTION 2

*Article 19*

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

Where economic operators make products available on the market online or through other means of distance sales, the offer of those products shall clearly and visibly indicate at least the following information:

(a) name, registered trade name or registered trade mark of the manufacturer, as well as the postal and electronic address at which they can be contacted;

(b) where the manufacturer is not established in the Union, the name, postal and electronic address of the responsible person within the meaning of Article 16(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; and

(d) any warning or safety information to be affixed to the product or to the packaging or included in an accompanying document in accordance with this Regulation or the applicable Union harmonisation legislation in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available on the market.

*Article 20*

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

1. The manufacturer shall ensure that, through the Safety Business Gateway, 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.

2. For the purpose of paragraph 1, the manufacturer shall notify the competent authorities of the occurrences associated with the use of a product that resulted in an individual's death or in serious adverse effects on that individual's health and safety, permanent or temporary, including injuries, other damage to the body, illnesses and chronic health effects.

3. 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 thereof. The manufacturer shall make the notification in accordance with paragraph 1 or instruct the importer or one of the distributors to make the notification.

4. Where the manufacturer of the product is not established in the Union, the responsible person within the meaning of Article 16(1) of this Regulation or Article 4(1) of Regulation (EU) 2019/1020 who has knowledge of an accident shall ensure that the notification is made.

*Article 21*

*Information in electronic format*

Without prejudice to Article 9(5), (6) and (7), Article 11(3) and Article 16(3), and the relevant provisions of Union harmonisation legislation, economic operators may additionally make the information referred to in those provisions 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 on the market, including in accessible formats for persons with disabilities.

# Chapter IV
# Providers of online marketplaces

*Article 22*

*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) 2022/2065, 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 4 of this Article.

   Providers of online marketplaces shall register with the Safety Gate Portal and shall indicate on the Safety Gate Portal the information concerning their single contact point.

2. Without prejudice to the general obligations provided for in Article 12 of Regulation (EU) 2022/2065, 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.

3. Providers of online marketplaces shall ensure that they have internal processes for product safety in place in order to comply without undue delay with the relevant requirements of this Regulation.

4. As regards powers conferred by Member States in accordance with Article 14 of Regulation (EU) 2019/1020, Member States shall confer on their market surveillance authorities the necessary power, as regards specific content referring to an offer of a dangerous product, to issue an order requiring the providers of online marketplaces to remove such content 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) 2022/2065.

Providers of online marketplaces shall take the necessary measures to receive and process 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 contact details of the market surveillance authority published in the Safety Gate Portal.

5. Orders issued pursuant to paragraph 4 may require the provider of an online marketplace, for the prescribed period, 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 of an online marketplace 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.

6. Providers of online marketplaces shall take into account regular information on dangerous products notified by the market surveillance authorities in line with Article 26, received through 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 online marketplace, where applicable, including by making use of the interoperable interface to the Safety Gate Portal in accordance with Article 34. They shall inform the authority that made the notification to the Safety Gate Rapid Alert System of any action taken by using the contact details of the market surveillance authority published in the Safety Gate Portal.

7. For the purpose of compliance with Article 31(3) of Regulation (EU) 2022/2065, as regards product safety, providers of online marketplaces shall use at least the Safety Gate Portal.

8. Providers of online marketplaces shall, without undue delay and in any event within three working days from the receipt of the notice, process the 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) 2022/2065.

9. For the purpose of compliance with the requirements of Article 31(1) and (2) of Regulation (EU) 2022/2065 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 that ensures that the information 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 16(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; and

(d) any warning or safety information 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 as determined by the Member State in which the product is made available on the market.

10. The internal processes referred to in paragraph 3 shall include mechanisms which enable traders to provide:

(a) information in accordance with paragraph 9 of this Article including information on the manufacturer established in the Union or, where applicable, the responsible person within the meaning of Article 16(1) of this Regulation or Article 4(1) of Regulation (EU) 2019/1020; and

(b) their self-certification committing to offer only products that comply with this Regulation and additional identification information, in accordance with Article 30(1) of Regulation (EU) 2022/2065, where applicable.

11. For the purpose of compliance with Article 23 of Regulation (EU) 2022/2065 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.

12. 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 the event 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 (the 'safety warning') in accordance with Article 35 or 36, or both;

(ii) publishing information on product safety recalls on their online interfaces;

(b) inform the relevant economic operator of the decision to remove or disable access to the content referring to an offer of a dangerous product;

(c) cooperate with market surveillance authorities and with relevant economic operators to ensure effective product recalls, including by abstaining from obstructing product recalls;

(d) immediately inform, through the Safety Business Gateway, the market surveillance authorities of the Member States in which the relevant product has been made available on the market about dangerous products that were offered on their online interfaces, of which they have actual knowledge, by providing the appropriate details available to them of the risk to the health and safety of consumers, of the quantity by Member State of products still circulating on the market, if available, and of any corrective measure that, to their knowledge, has already been taken;

(e) cooperate with regard to accidents notified to them, including by:

(i) informing the relevant traders and economic operators without delay about the information they have received regarding accidents or safety issues, where they have knowledge that the product in question was offered by those traders through their interfaces;

(ii) notifying without undue delay through the Safety Business Gateway of any accident, of which they have been informed, resulting in a serious risk or actual damage to the health or safety of a consumer, caused by a product made available on their online marketplace and inform the manufacturer thereof;

(f) cooperate with law enforcement agencies at Union and national level, including the European Anti-Fraud Office (OLAF), through regular and structured exchange of information on offers that have been removed on the basis of this Article by providers of online marketplaces;

(g) allow access to their interfaces for the online tools operated by market surveillance authorities to identify dangerous products;

(h) cooperate in identifying, as far as possible, the supply chain of dangerous products by responding to data requests where the relevant information is not publicly available;

(i) 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.

# Chapter V
# Market surveillance and implementation

*Article 23*

*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 apply 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, 16, 18 and 23 of that Regulation shall be read as references to ‘this Regulation’;

   (b) reference to ‘that legislation and this Regulation’ in Article 11(1), point (b) of that Regulation shall be read as a reference to ‘this Regulation’;

(c) references to ‘Network’ in Articles 11 to 13 and Article 21 of that Regulation shall be read as references to ‘Network and Consumer Safety Network referred to in Article 30 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 that Regulation 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 that Regulation shall be read as a reference to ‘Article 44 of this Regulation’;

(f) the reference to ‘Article 20’ in Article 19(1) of that Regulation shall be read as a reference to ‘Article 26 of this Regulation’.

3. Where a dangerous product has been identified, market surveillance authorities may request from the manufacturer information on other products, produced using the same procedure, containing the same components or being part of the same production batch, which are affected by the same risk.

*Article 24*

*Reporting*

1. Member States shall communicate to the Commission, not later than two years after the adoption of the implementing act referred to in paragraph 2 and every year thereafter, data concerning the application of this Regulation.

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

2. The Commission shall, by means of implementing acts, determine the output indicators on the basis of which Member States are to communicate the data referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 46(3).

# Chapter VI

# Safety Gate Rapid Alert System and Safety Business Gateway

*Article 25*

*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') and 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 be responsible at least for checking the completeness of the notifications and for the submission thereof for validation by the Commission, as well as for communication with the Commission with regard to the tasks provided for in Article 26(1) to (6).

   The Commission shall adopt an 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 46(3).

*Article 26*

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

1. Member States shall notify through the Safety Gate Rapid Alert System corrective measures taken by their authorities or by economic operators on the basis of:

   (a) provisions of this Regulation, in relation to dangerous products presenting a serious risk to the health and safety of consumers; and

   (b) Article 20 of Regulation (EU) 2019/1020.

2. Member States may also notify envisaged corrective measures in relation to products presenting a serious risk through the Safety Gate Rapid Alert System if they consider it necessary with regard to the urgency of the risk to the health or safety of consumers.

3. Without prejudice to paragraph 1 of this Article, Member States shall inform the Commission about corrective measures taken by their authorities or by economic operators on the basis of this Regulation and the Commission shall forward that information to the other Member States. For that purpose, Member States may notify through the Safety Gate Rapid Alert System corrective measures taken by their authorities or by economic operators on the basis of this Regulation, of Union harmonisation legislation and of Regulation (EU) 2019/1020 in relation to products presenting a less than serious risk.

4. The national authorities shall submit notifications as referred to in paragraph 1 through the Safety Gate Rapid Alert System without delay and in any event within four working days after the corrective measure is taken.

5. 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 10. If the notification complies with this Article and those requirements, the Commission shall transmit it to the other Member States.

6. Member States shall notify through the Safety Gate Rapid Alert System without undue delay any update, modification or withdrawal of the corrective measures referred in paragraphs 1, 2 and 3.

7. Where a Member State notifies corrective measures taken in relation to products presenting a serious risk, the other Member States shall notify through 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.

8. 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 through the Safety Gate Rapid Alert System, it shall inform the Member States thereof. Member States shall undertake the appropriate verifications and, if they adopt measures, notify them through the Safety Gate Rapid Alert System in accordance with paragraph 1.

9. 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 that Regulation and the Safety Gate Rapid Alert System to enable a draft Safety Gate Rapid Alert System notification to be triggered from that information and communication system in order to avoid double data entry.

10. The Commission shall adopt delegated acts in accordance with Article 45 to supplement this Regulation by specifying, in particular:

(a) the access to the Safety Gate Rapid Alert System;

(b) the operation of the Safety Gate Rapid Alert System;

(c) the information to be entered in the Safety Gate Rapid Alert System;

(d) the requirements notifications must meet; and

(e) the criteria for assessment of the level of risk.

*Article 27*

*Safety Business Gateway*

1. The Commission shall maintain a web portal enabling economic operators and providers of online marketplaces to provide, in an easy way, market surveillance authorities and consumers with the information referred to in Article 9(8) and (9), Article 10(2), point (c), Article 11(2) and (8), Article 12(4), Articles 20 and 22 (the ‘Safety Business Gateway’).

2. The Commission shall draw up guidelines for the practical implementation of the Safety Business Gateway.

# Chapter VII
# Commission's role and enforcement coordination

*Article 28*

*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:

   (a) 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 law applicable to the products concerned; and

   (b) the risk can be eliminated in an effective manner 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 for their marketing, such as representative sample testing of those products, in order to ensure a high level of consumer safety protection.

Member States shall, within their jurisdiction, take all appropriate enforcement measures necessary to ensure the effective implementation of those implementing acts. The competent authorities of the Member States concerned shall inform the Commission of the enforcement measures taken.

The Commission shall regularly evaluate the efficiency of the enforcement measures taken by Member States and inform the Consumer Safety Network of the outcome of that evaluation.

2. The implementing acts referred to in the paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 46(3). Those implementing acts shall specify the date on which they 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 46(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 paragraph 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 paragraph 3.

*Article 29*

*Request for an opinion from the Commission on divergences in risk assessment*

1. Products that have been deemed to be dangerous on the basis of a decision of a market surveillance authority in one Member State under this Regulation shall be presumed dangerous by market surveillance authorities in other Member States.

2. Where market surveillance authorities in different Member States reach divergent conclusions 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, requesting its opinion on the matter and the Commission shall, without undue delay, issue an opinion on the identification or on the level of the risk of the relevant product, as appropriate. 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 an opinion referred to in this paragraph, the Commission may ask for relevant information and documents and shall invite all Member States to express their views.

3. Where the Commission issues an opinion pursuant to paragraph 2, the Member States shall take it into due account.

4. The Commission shall draw up guidelines for the practical implementation of this Article.

5. The Commission shall periodically draw up a report on the application of this Article and shall present it to the Consumer Safety Network.

*Article 30*

*Consumer Safety Network*

1. A European network of the authorities of the Member States competent for product safety (the '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 in enhancing 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 tasks 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 for the collection of data, interoperability of information and communication systems, recent scientific developments and the 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 32; and

(f) 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.

5. The Consumer Safety Network shall adopt its work programme, which, inter alia, shall set out the priorities for safety of the products and for the risks 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.

6. The Consumer Safety Network shall be duly represented and regularly participate in the relevant activities of 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 31*

*Joint activities on product safety*

1. In the framework of the activities referred to in Article 30(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 made available on the market, in particular categories of products that are often found to present a serious risk to the health and safety of consumers.

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 those parties.

3. The Commission shall organise on a regular basis joint activities of market surveillance authorities whereby the market surveillance authorities conduct inspections regarding products offered online or offline, which those authorities acquired under a cover identity.

4. A market surveillance authority may use any information obtained as a result of the joint activities carried out as part of any investigation undertaken by it regarding the safety of products.

5. 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 that agreement available on the Safety Gate Portal.

*Article 32*

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

1. The market surveillance authorities concerned shall conduct simultaneous coordinated control actions ('sweeps') of particular products or categories of products with the objective of checking 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 to a remedy

*Article 33*

*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 the health and safety of consumers 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. That information shall also 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. That information shall be treated as 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 the case of product recalls are not satisfactory. Such complaints shall be followed up appropriately. The competent authorities shall provide the complainant with appropriate information on the follow-up, in accordance with national law.

*Article 34*

*Safety Gate Portal*

1. For the purpose of Article 9(9), Articles 20 and 22, Article 31(5) and Article 33(1), the Commission shall maintain a Safety Gate Portal, providing the general public with free of charge and open access to selected information notified in accordance with Article 26 (the ‘Safety Gate Portal’).

2. The Safety Gate Portal shall have an interface which is intuitive for users and the information provided on that portal shall be easily accessible by the public, including by persons with disabilities.

3. Consumers and other interested parties shall have the possibility to inform the Commission of products that might present a risk to the health and safety of consumers through a separate section of the Safety Gate Portal. The Commission shall give due consideration to the information received and, after verification of its accuracy, where appropriate, forward that information to the relevant Member States without undue delay to ensure that that information is appropriately followed-up. The Commission shall inform consumers and other interested parties of its action.

4. The Commission shall, by means of an implementing act, adopt the modalities for the sending of information by consumers in accordance with paragraph 3, as well as for the transmission of such information to the national authorities concerned for possible follow up. This implementing act shall be adopted in accordance with the examination procedure referred to in Article 46(3).

5. By … [*18 months after the date of entry into force 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.

6. The Commission shall adopt implementing acts specifying the implementation of the interoperable interface on the Safety Gate Portal in accordance with paragraph 5, 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 46(3).

*Article 35*

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

1. In the 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 9, 10, 11 and 12, and providers of online marketplaces in accordance with their obligations as provided for in Article 22(12), 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 that 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-related purposes. The personal data collected for that purpose shall be limited to the necessary minimum and shall only be used to contact consumers in the event of a recall or safety warning.

3. The Commission may, by means of implementing acts, 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 the case of a product safety recall or safety warning in relation to that product, in accordance with paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 46(3).

4. Where not all of the affected consumers can be contacted under 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 persons with disabilities.

*Article 36*

*Recall notice*

1. Where information on a product safety recall is provided to consumers in a written form, in accordance with Article 35(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 made available on the market and include the following elements:

   (a) a headline consisting of the words 'Product safety recall';

   (b) a 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; and

(iii) information on when, where and by whom the product was sold, if available;

(c) a clear description of the hazard associated with the recalled product, avoiding any elements that may decrease consumers' perception of risk, such as by using terms and expressions such as 'voluntary', 'precautionary', 'discretionary', 'in rare situations' or 'in specific situations' or by indicating that there have been no reported accidents;

(d) a clear description of the action consumers should take, including an instruction to immediately stop using the recalled product;

(e) a clear description of the remedies available to consumers in accordance with Article 37;

(f) a free phone number or interactive online service, where consumers can get more information in relevant official language(s) of the Union; and

(g) encouragement to share the information about the recall with other persons, if appropriate.

3. The Commission shall, by means of implementing acts, 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 46(2). That template shall be made available by the Commission in a format that enables economic operators to easily create a recall notice, including in accessible formats for persons with disabilities.

*Article 37*

*Remedies in the event of a product safety recall*

1. Without prejudice to Directives (EU) 2019/770 and (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 product safety recall shall offer the consumer an effective, cost-free and timely remedy.

2. Without prejudice to any other remedies that the economic operator responsible for the recall may offer the consumer, the economic operator shall offer the consumer the choice between at least two of the following remedies:

   (a) the repair of the recalled product;

(b) a replacement of the recalled product with a safe one of the same type and at least the same value and quality; or

(c) an 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.

By way of exception to the first subparagraph, the economic operator may offer the consumer only one remedy where other remedies would be impossible or, compared to the proposed remedy, would impose costs on the economic operator responsible for the product safety recall 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 product safety recall has not completed the repair or replacement within a reasonable time and without significant inconvenience to the consumer.

3. Repair by a consumer shall only be considered an effective remedy where it can be carried out easily and safely by the consumer and where envisaged in the recall notice. In such cases, the economic operator responsible for the product safety 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 Directives (EU) 2019/770 and (EU) 2019/771.

4. Disposal of the product by consumers shall only be included in the actions to be taken by consumers under Article 36(2), point (d) where such disposal can be carried out easily and safely by the consumer, and shall not affect the right of the consumer to receive a refund for or replacement of the recalled product under paragraph 1 of this Article.

5. 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 38*

*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, aimed at undertaking voluntary commitments to enhance 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 law.

*Article 39*

*Representative actions*

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 40*

*International cooperation*

1. In order to improve the overall level of safety of products made available on the 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 such cooperation shall be based on reciprocity, shall include provisions on confidentiality corresponding to those applicable in the Union and shall ensure that any exchange of information take place 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;

(f) use of new technologies to improve product safety and increase traceability in the supply chain;

(g) standardisation-related activities;

(h) 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 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; or

(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 law 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 those agreements.

5. Any information exchange under this Article shall, to the extent it involves personal data, 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 the health or safety of consumers.

6. The information exchanged pursuant to this Article shall be used for the sole purpose of the protection of the health or safety of consumers.

# Chapter X
# Financial provisions

*Article 41*

*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;

   (b) the development and operation of the Safety Gate Rapid Alert System, including the development of electronic interoperability solutions for the exchange of data:

      (i) between the Safety Gate Rapid Alert System and the national market surveillance systems;

      (ii) between the Safety Gate Rapid Alert System and customs systems;

      (iii) with other relevant restricted systems used by market surveillance authorities for their enforcement purposes;

(c) the development and maintenance of the Safety Gate Portal and the Safety Business Gateway, 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 40;

(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) 2018/1046 of the European Parliament and of the Council[1], 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 European Parliament and the Council within the limits of the financial framework in force.

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[1] 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).

5. The appropriations determined by the European Parliament and the Council 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 insofar 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.

*Article 42*

*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 in accordance with the provisions and procedures laid down in Council Regulation (Euratom, EC) No 2185/96[1].

3. 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[2] and Regulation (Euratom, EC) No 2185/96, 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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1 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).

2 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).

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 43*

*Liability*

1. Any decision taken pursuant to this Regulation that imposes restrictions on the placing of or making a product available on the market or requires its withdrawal or its recall shall not affect the assessment of the liability of the party concerned, in the light of the national law applicable in the case in question.

2. This Regulation shall not affect Council Directive 85/374/EEC[1].

[1] 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).

*Article 44*

*Penalties*

1. 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.

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

*Article 45*

*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 Article 18(3) and Article 26(10) shall be conferred on the Commission for an indeterminate period of time from … [*the date of entry into force of this Regulation*].

3. The delegation of power referred to in Article 18(3) and Article 26(10) 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 of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 18(3) or Article 26(10) 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 shall be extended by two months at the initiative of the European Parliament or of the Council.

*Article 46*

*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 47*

*Evaluation and review*

1. By … [*78 months after the date of entry into force of this Regulation*] the Commission shall carry out an evaluation of this Regulation. The Commission shall submit to the European Parliament, the Council and to the European Economic and Social Committee a report on the main findings. That report shall assess whether this Regulation, and in particular Articles 18, 22 and 25, 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 SMEs.

2. By … [*78 months after the date of entry into force of this Regulation*], the Commission shall draw up an evaluation report on the implementation of Article 16. 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.

3. By … [*54 months after the date of entry into force 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 22(4), (5) and (6) by means of a Union notification system designed and developed within the Safety Gate Portal. Such assessment shall be accompanied, where appropriate, by a legislative proposal.

4. By … [*42 months after the date of entry into force of this Regulation*] the Commission shall publish a report on the functioning of the interconnection between information and communication system referred to in Article 34 of Regulation (EU) 2019/1020 and the Safety Gate Portal referred to in this Regulation, including information on their respective functionalities, further improvements or on the development of a new interface, if appropriate.

5. By … [*78 months after the date of entry into force of this Regulation*], the Commission shall draw up an evaluation report on the implementation of Article 44. 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.

6. On request, Member States shall provide the Commission with information necessary for the evaluation of this Regulation.

*Article 48*

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

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

(1) in Article 10, the following paragraph is added:

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

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[*] Regulation (EU) …/… of the European Parliament and of the Council of … 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 Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (OJ L …, …, p. …).’;

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[+] OJ: Please insert in the text the number of the Regulation contained in document PE-CONS 79/22 (2021/0170(COD)) and insert the number, date and OJ reference of that Regulation in the footnote.

(2) 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) …/…[+] 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 that Regulation, 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 concerned drafted in support of that Regulation in the *Official Journal of the European Union;* and

(b) to maintain, to maintain with restriction or to withdraw the references to the harmonised standard or European standard concerned drafted in support of that Regulation 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) …/…[+] that have been subject to a decision pursuant to paragraph 1.

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[+] OJ: Please insert in the text the number of the Regulation contained in document PE-CONS 79/22 (2021/0170(COD)).

3. The Commission shall inform the European standardisation organisation concerned of any decision adopted pursuant to paragraph 1 and, if necessary, request the revision of the harmonised standards or of the European standards concerned drafted in support of Regulation (EU) …/…[+].'.

*Article 49*

*Amendment to Directive (EU) 2020/1828*

In Annex I to Directive (EU) 2020/1828, point (8) is replaced by the following:

'(8) Regulation (EU) …/…[++] of the European Parliament and of the Council of … 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 Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (OJ L …, …, p. …).'.

*Article 50*

*Repeal*

1. Directives 87/357/EEC and 2001/95/EC are repealed with effect from … [*18 months after the date of entry into force of this Regulation*].

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[+] OJ: Please insert in the text the number of the Regulation contained in document PE-CONS 79/22 (2021/0170(COD)).

[++] OJ: Please insert in the text the number, date and OJ reference of the Regulation contained in document PE-CONS 79/22 (2021/0170(COD)).

2. References to the repealed directives 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 to this Regulation.

*Article 51*

*Transitional provision*

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 52*

*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 date of entry into force of this Regulation*].

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

Done at …,

| | |
|---|---|
| *For the European Parliament* | *For the Council* |
| *The President* | *The President* |

**ANNEX**

Correlation Table

| Directive 87/357/EEC | Directive 2001/95/EC | Regulation (EU) No 1025/2012 | This Regulation |
|---|---|---|---|
| | Article 1(2) | | Article 2(1) and (2) |
| | Article 2 except point (a), 2nd subparagraph and point (b), 2nd subparagraph | | Article 3 |
| | Article 2, point (a), 2nd subparagraph | | Article 2(2), point (i) and Article 2(3) |
| | Article 2, point (b), 2nd subparagraph | | Article 6(2) |
| | Article 3(1) | | Article 5 |
| | Article 3(2) | | Article 7(1) |
| | Article 3(3) | | Article 8 |
| | Article 3(4) | | Article 7(3) |
| | Article 4(1), points (a) and (b) | Article 10(1) | Article 7(2) |
| | Article 4(1), point (c) | - | - |
| | Article 4(1), point (d) | - | - |

| Directive 87/357/EEC | Directive 2001/95/EC | Regulation (EU) No 1025/2012 | This Regulation |
|---|---|---|---|
| | Article 4(2), first subparagraph | Article 10(7) | Article 48(1), point (a) |
| | Article 4(2), second subparagraph | - | - |
| | Article 4(2), third and fourth subparagraphs | Article 11(1), point (b) | Article 48(1), point (b) |
| | Article 5(1), first subparagraph | | Article 9(7) |
| | Article 5(1), second subparagraph | | - |
| | Article 5(1), third subparagraph, point (a) | | Article 9(10), (12) and (13) and Article 11(9) and (10) |
| | Article 5(1), third subparagraph, point (b) | | Article 9(8) and Article 11(8) |
| | Article 5(1), fourth subparagraph, point (a) | | Article 9(5) and (6) and Article 11(3) |
| | Article 5(1), fourth subparagraph, point (b), first sentence | | Article 9(2) and (3) |
| | Article 5(1), fourth subparagraph, point (b), second sentence | | Article 9(11), (12) and (13) and Article 11(9), (10) and (11) |

| Directive 87/357/EEC | Directive 2001/95/EC | Regulation (EU) No 1025/2012 | This Regulation |
|---|---|---|---|
| | Article 5(1), fifth subparagraph | | Article 9(8), point (a) |
| | Article 5(2) | | Article 12(1) and (3) |
| | Article 5(3), first subparagraph | | Article 9(8), Article 11(8) and Article 12(4) |
| | Article 5(3), second subparagraph | | - |
| | Article 5(4) | | Article 15 |
| | Articles 6 to 9 | | Article 2(2), Articles 23 and 44 |
| | Article 10(1) | | Article 30 |
| | Article 10(2) | | Articles 31 and 32 |
| | Article 11(1), first subparagraph | | Article 26(3) |
| | Article 11(1), second subparagraph | | - |
| | Article 11(1), third subparagraph | | Article 26(10) |

| Directive 87/357/EEC | Directive 2001/95/EC | Regulation (EU) No 1025/2012 | This Regulation |
|---|---|---|---|
| | Article 11(2) | | Article 26(5) |
| | Article 12(1), first and fourth subparagraph | | Article 26(1) and (2) |
| | Article 12(1), second subparagraph | | - |
| | Article 12(1), third subparagraph | | - |
| | Article 12(2) | | Article 26(5) and (7) |
| | Article 12(3) | | Article 26(10) |
| | Article 12(4) | | Article 40(2) to (6) |
| | Article 13 | | Article 28 |
| | Articles 14 and 15 | | Article 46 |
| | Article 16(1), first subparagraph | | Article 33(1) |
| | Article 16(1), second subparagraph | | Article 33(2) |
| | Article 16(2) | | Article 33(3) |
| | Article 17 | | Article 43(2) |

| Directive 87/357/EEC | Directive 2001/95/EC | Regulation (EU) No 1025/2012 | This Regulation |
|---|---|---|---|
| | Article 18(1) and (2) | | Article 23 |
| | Article 18(3) | | Article 43(1) |
| | Article 19(1) | | - |
| | Article 19(2) | | Article 47 |
| | Article 20 | | - |
| | Article 21 | | Article 52 |
| | Annex I, (1) | | Article 9(8), Article 10(2), point (c), Article 11(8) and Article 12(4) |
| | Annex I, (2) and (3) | | Article 26 |
| | Annex III | | - |
| | Annex IV | | Annex |
| Articles 1 and 2 | | | Article 6(1), first subparagraph and Article 6(1)(f), point (i) |
| Articles 3 to 7 | | | - |