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From:	Presidency
To:	Delegations
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 repealing Council Directive 87/357/EEC and Directive 2001/95/EC of the European Parliament and of the Council - Presidency compromise proposal on Block 1 (chapters I, II and V)

In view of the Working Party on Consumer Protection and Information meeting on 20 January 2022, delegations will find in Annex to this note a Presidency compromise proposal on Block 1 (chapters I, II and V and related recitals).

Changes compared to the Commission proposal (doc. 10381/21) are marked in **bold underlined** for new text and ~~strikethrough~~ for deleted text.

ANNEX

PRESIDENCY COMPROMISE PROPOSAL ON CHAPTERS I, II AND V

14/01/2022

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(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,

Whereas:

[1] .OJ C , , p. .

(1) Directive 2001/95/EC of the European Parliament and of the Council[2] lays down the requirement that consumer products must be safe and that Member States' market surveillance authorities must take action against dangerous products as well as exchange information to that effect through the "Union rapid information exchange system", RAPEX.

(2) Directive 2001/95/EC needs to be revised and updated in light of the developments related to new technologies and online selling, to ensure consistency with developments in the Union harmonisation legislation and in the standardisation legislation, to ensure a better functioning of the product recalls as well as to ensure a clearer framework for food-imitating products so far regulated by Council Directive 87/357/EEC[3]. In the interest of clarity, Directive 2001/95/EC, as well as Directive 87/357/EEC, should be repealed and replaced by this Regulation.

(3) A Regulation is the appropriate legal instrument as it imposes clear and detailed rules which do not give room for divergent transposition by Member States. The choice of Regulation instead of Directive also allows to better deliver on the objective to ensure coherence with the market surveillance legislative framework for products falling under the scope of Union harmonisation legislation as set out in Regulation (EU) 2019/1020, where the applicable legal instrument is also of the same type, namely Regulation (EU) 2019/1020 of the European Parliament and of the Council[4]. Finally, such a choice will further reduce the regulatory burden through a consistent application of product safety rules across the Union.

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

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

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

(4) The aim of this instrument is to contribute to the attainment of the objectives referred to in Article 169 of the Treaty. In particular, it should aim at ensuring health and safety of consumers and the functioning of the internal market as regards products intended for consumers.

(5) This Regulation should aim at protecting consumers and their safety as one of the fundamental principle of the EU legal framework, enshrined in the EU Charter of fundamental rights. Dangerous products can have very negative consequences on consumers and citizens. All consumers, including the most vulnerable, such as children, older persons or persons with disabilities, have the right to safe products. Consumers should have at their disposal sufficient means to enforce such rights, and Member States adequate instruments and measures at their disposal to enforce this Regulation.

(6) Despite the development of sector-specific Union harmonisation legislation that addresses safety aspects of specific products or categories of products, it is practically impossible to adopt Union legislation for all consumer products that exist or may be developed. There is therefore still a need for a legislative framework of a horizontal nature to fill gaps and ensure consumer protection not otherwise ensured, in particular with a view to achieving a high level of protection of safety and health of consumers, as required by Article 114 and Article 169 of the Treaty.

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

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

(8a) Pursuant to Regulation (EU) 2013/952, products from third countries intended to be made available on the Union market or intended for private use or consumption within the customs territory of the Union are placed under the customs procedure 'release for free circulation'. This procedure aims at completing the formalities laid down in respect of the import of the goods, including the enforcement of the applicable provisions of Union law, so that these goods can be made available on the Union market like any product made in the Union. As far as consumer safety is concerned, these products are required to comply with this Regulation and, in particular, with the general safety requirement laid down in Article 5.

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

(9) The provisions of Chapter VII of Regulation (EU) 2019/1020, setting up the rules of controls on products entering the Union market, are already directly applicable to products covered by this Regulation and it is not the intention of this Regulation to modify such provisions. The stability of the former is particularly important taking into account the fact that the authorities in charge of these controls (which in almost all Member States are the customs authorities) shall perform them on the basis of risk analysis as referred to in Articles 46 and 47 of Regulation (EU) No 952/2013 (the Union Customs Code), the implementing legislation and corresponding guidance. This risk-based approach is pivotal to customs controls given the substantial volumes of goods coming into and leaving the customs territory and results in application of concrete control measures depending on identified priorities. The fact that the Regulation does not modify in any way Chapter VII of Regulation 2019/1020, directly referring to the risk based approach laid down in the customs legislation, means in practice that the authorities in charge of controls on products entering the Union market (including customs authorities) should limit their controls to the most risky products, depending on the likelihood and impact of the risk, thereby ensuring effectiveness and efficiency of their activities as well as protection of their capacity to perform such controls.

(10) **Technological changes accompany new type of products as well as new or emerging risks linked to a high degree of scientific uncertainty. Especially, but not only in these situations,** ~~The~~ **the** precautionary principle is a fundamental principle for ensuring the safety of products and consumers and should therefore be taken into due account by all relevant actors when applying this Regulation. **Where an activity or substance poses a plausible threat of harm but there is insufficient scientific evidence, or a lack of agreement as to the nature or scale of the likely adverse effects, the precautionary principle should lead the different actors in taking decisions. The precautionary principle thus expresses a need for caution with regard to products or action which are not based on a high degree of scientific certainty.**

(11) Considering also the broad scope given to the concept of health[6], the environmental risk posed by a product should be taken into consideration in the application of this Regulation inasmuch as it can also ultimately result in a risk to the health and safety of consumers.

(12) Products which are designed exclusively for professional use but which have subsequently migrated to the consumer market should be subject to this Regulation because they could pose risks to the health and safety of consumers when used under reasonably foreseeable conditions.

(13) Union legislation on food, feed and related areas sets up a specific system ensuring the safety of the products covered by it. Therefore, food and feed should be excluded from the scope of this Regulation with the exception of materials and articles intended to come into contact with food insofar as risks are concerned that are not covered by Regulation (EC) No 1935/2004 of the European Parliament and of the Council[7] or by other food specific legislation which only covers chemical and biological food-related risks.

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

(15) Aircraft referred to in Article 2(3) point (d) of Regulation (EU) 2018/1139[8] are subject to the regulatory control of the Member States, in light of their limited risk to civil aviation safety. They should therefore be excluded from the scope of this Regulation.

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6 European Environment Agency, 'Healthy environment, healthy lives: how the environment influences health and well-being in Europe', EEA report No 21/2019, 8 September 2020.

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

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

(16) The requirements laid down in this Regulation should apply to second hand products or products that are repaired, ~~refurbished~~ **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 antiques or products which are presented as to be repaired or to be ~~refurbished~~ **reconditioned**.

(17) Directive 87/357/EEC on consumer products which, although not foodstuff, resemble foodstuff and are likely to be confused with foodstuff in a way that consumers, especially children, may place them in their mouths, suck or ingest them and which might cause, for example, suffocation, poisoning, the perforation or obstruction of the digestive tract, has given rise to controversial interpretation. Furthermore it has been adopted at a time where the legal framework for consumer product safety was very limited in scope. For these reasons, Directive 87/357/EEC should be repealed.

(18) Services should not be covered by this Regulation. However, in order to secure the attainment of the protection of health and safety of consumers, products that are supplied or made available to consumers in the context of the provision of services, including products to which consumers are directly exposed during a service provision, should fall within the scope of this Regulation. Equipment on which consumers ~~ride or~~ travel **but** which is ~~operated~~ **driven** by a service provider should be excluded from the scope of this Regulation since it has to be dealt with in conjunction with the safety of the service provided.

(18a) Given the potential risk of non-tangible items such as software, not only when they are embedded into another product but also as stand-alone items, the definition of 'product' should be as broad as to include them.

(18b) According to the general safety requirement laid down in Article 5 of this Regulation, economic operators are obliged to place only safe products on the market. In determining whether a product is safe, the different actors should take into consideration not only the normal conditions in which the product is intended to be used, but also its foreseeable conditions of use, even if these conditions are not necessarily the intended ones. This means that the economic operators should take into consideration the possibility that the product is misused, that is to say used in a way that was not necessarily intended, in case such a misuse is reasonably foreseeable. A product which could be foreseeably misused may be placed on the market, provided that certain safeguards, such as warnings or other measures, accompany it. In any case, the reasonably foreseeable misuse of the product should not include reckless, malevolent or criminal behaviour.

(19) Items which connect to other items or non-embedded items which influence the way another item works can present a risk for the safety of the product. That aspect should be taken into due consideration as a potential risk. The ~~connections~~ **interconnections** and interrelation ~~that an item might have with external items~~**, and therefore the possibility to digitally or physically interact with another item,** should not jeopardise its safety.

(20) New technologies also cause 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.

(21) The World Health Organisation defines 'health' as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. This definition supports the fact that the development of new technologies might bring new health risks to consumers, such as psychological risk, development risks, in particular for children, mental risks, depression, loss of sleep, or altered brain function.

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

(23) The safety of products should be assessed taking into account all the relevant aspects, notably their characteristics and presentation as well as the specific needs and risks for categories of consumers who are likely to use the products, in particular children, older persons and persons with disabilities. Therefore, if specific information is necessary to make products safe toward a given category of persons, the assessment of the safety of the products should take into consideration also the presence of this information and its accessibility. The safety of products should be assessed taking into consideration the need for the product to be safe over its entire lifespan.

(24) Economic operators should have 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. 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.

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

(25a) Union product safety legislation also applies to cases where online sellers based outside the Union target consumers or other end users within the Union. Therefore it should be established whether the offer from the online seller based outside the Union targets consumers or other end users within the Union in order to assess whether a product is placed on the Union market.

On the basis of the Court of Justice of the European Union case-law, the assessment must be done on a case-by-case basis. The following aspects should in particular be considered: the international nature of the activity, the use of a language and currency of the Member States, a domain name registered in one of the Member States, and the geographical areas to which dispatch is possible. If an online operator delivers to adresses in the EU, accepts currencies used in the Member States as payment for the product from end users within the Union and uses any Union official language, it can be considered that the operator has directed its activites to Union consumers or other end users within the Union. The physical fulfilment to end users within the Union of an order for a product from a given online seller based outside the Union, including by a fulfilment service provider regardless of whether it is based within or outside the Union, should give confirmation that a product is placed on the Union market. Therefore, if the manufacturers or distributors are based outside the Union and direct their offers of products for sale online to the Union market, they should comply with the requirements laid down by this Regulation.

(26) Online marketplaces play a crucial role in the supply chain - allowing economic operators to reach an indefinite number of consumers - and therefore also in the product safety system.

(27) Given the important role played by 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[9] provides the general framework for e-commerce and lays down certain obligations for online platforms. Regulation […/…] on a Single Market for Digital Services (Digital Services Act) and amending Directive 2000/31/EC[10] regulates the responsibility and accountability of providers of intermediary services online with regard to illegal contents, including unsafe products. That Regulation applies without prejudice to the rules laid down by Union law on consumer protection and product safety. Accordingly, building on the horizontal legal framework provided by that Regulation, specific requirements essential to effectively tackle the sale of dangerous products online should be introduced, in line with Article [1(5), point (h)] of that Regulation.

(28) The Product Safety Pledge, signed in 2018 and joined by a number of marketplaces since then, provides for a number of voluntary commitments on product safety. The Product Safety Pledge has proved its rationale in enhancing the protection of consumers against dangerous products sold online. Nonetheless, its voluntary nature and the voluntary participation by a limited number of online marketplaces reduces its effectiveness and cannot ensure a level-playing field.

(29) Online marketplaces should act with due care in relation to the content hosted on their online interfaces that concerns safety of products, in accordance with the specific obligations laid down in this Regulation. Accordingly, due diligence obligations for all online marketplaces should be established in relation to the content hosted on their online interfaces that concerns safety of products.

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

[10] Regulation […/…] on a Single Market for Digital Services (Digital Services Act) and amending Directive 2000/31/EC.

(30) Moreover, for the purposes of effective market surveillance, online marketplaces should register in the Safety Gate portal and indicate, in the same portal, the information concerning their single contact points for the facilitation of communication of information on product safety issues. The single point of contact under this Regulation might be the same as the point of contact under [Article 10] of Regulation (EU) …/…[*the Digital Services Act*], without endangering the objective of treating issues linked to product safety in a swift and specific manner.

(31) In order to be able to comply with their obligations under this Regulation, in particular in respect of timely and effective compliance with the orders of public authorities, processing of notices of other third parties and cooperating with market surveillance authorities in the context of corrective measures upon request, online marketplaces should have in place an internal mechanism for handling product safety-related issues.

(32) The obligations imposed by this Regulation on online marketplaces should neither amount to a general obligation to monitor the information which they transmit or store, nor to actively seek facts or circumstances indicating illegal activity, such as the sale of dangerous products online. Online marketplaces should, nonetheless, expeditiously remove content referring to dangerous products from their online interfaces, upon obtaining actual knowledge or, in the case of claims for damages, awareness of the illegal content, in particular in cases where the online marketplace has been made aware of facts or circumstances on the basis of which a diligent economic operator should have identified the illegality in question, in order to benefit from the exemption from liability for hosting services under the 'Directive on electronic commerce' and the [Digital Services Act]. Online marketplaces should process notices concerning content referring to unsafe products, received in accordance with [Article 14] of Regulation (EU) …/…[*the Digital Services Act*], within the additional timeframes established by this Regulation.

(33) Article 14(4) of Regulation (EU) 2019/1020 provides market surveillance authorities with the power, where no other effective means are available to eliminate a serious risk, to require the removal of content referring to the related products from an online interface or to require the explicit display of a warning to end users when they access an online interface. The powers entrusted to market surveillance authorities by Article 14(4) of Regulation (EU) 2019/1020 should also apply to this Regulation. For effective market surveillance under this Regulation and to avoid dangerous products being present on the Union market, this power should apply in all necessary and proportionate cases and also for products presenting a less than serious risk. It is essential that online marketplaces comply with such orders as a matter of urgency. Therefore, this Regulation introduces binding time limits in this respect, without prejudice to the possibility for a shorter time limit to be laid down in the order itself. This power should be exercised in accordance with [Article 8] of the Digital Services Act.

(34) Even where the information from the Safety Gate does not contain an exact uniform resource locator (URL) and, where necessary, additional information enabling the identification of the illegal content concerned, 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 online marketplaces on their own initiative aiming at detecting, identifying, removing or disabling access to dangerous products offered on their marketplace, where applicable.

(35) For the purposes of [Article 19] of Regulation (EU) …/…[*the Digital Services Act*], and concerning the safety of products sold online, the Digital Services Coordinator should consider in particular consumer organisations and associations representing consumers' interest, upon their request, as trusted flaggers, provided that the conditions set out in that article have been met.

(36) Product traceability is fundamental for effective market surveillance of dangerous products and corrective measures. Consumers should also be protected against dangerous products in the same way in the offline and online sales channels, including when purchasing products on online marketplaces. Building on the provisions of Regulation (EU) …/…[*the Digital Services Act*]concerning the traceability of traders, online marketplaces should not allow listings on their platforms unless the trader provided all information related to product safety and traceability as detailed in this Regulation. Such information should be displayed together with the product listing so that consumers can benefit from the same information made available online and offline. However, the online marketplace should not be responsible for verifying the completeness, correctness and the accuracy of the information itself, as the obligation to ensure the traceability of products remains with the trader.

(37) It is also important that online marketplaces closely cooperate with the market surveillance authorities, law enforcement authorities and with relevant economic operators on the safety of products. An obligation of cooperation with market surveillance authorities is imposed on information society service providers under Article 7(2) of Regulation (EU) 2019/1020 in relation to products covered by that Regulation and should therefore be extended to all consumer products. For instance, market surveillance authorities are constantly improving the technological tools they use for the online market surveillance to identify dangerous products sold online. For these tools to be operational, online marketplaces should grant access to their interfaces. Moreover, for the purpose of product safety, market surveillance authorities may also need to scrape data from the online marketplaces.

(38) Direct selling by economic operators established outside the Union through online channels hinders the work of market surveillance authorities when tackling dangerous products in the Union, as in many instances economic operators may not be established nor have a legal representative in the Union. It is therefore necessary to ensure that market surveillance authorities have adequate powers and means to effectively tackle the sale of dangerous products online. In order to ensure an effective enforcement of this Regulation, the obligation set out in Article 4(1), (2) and (3) of Regulation 2019/1020 should be extended also to products falling outside the scope of the Union harmonisation legislation to ensure that there is a responsible economic operator established in the Union, which is entrusted with tasks regarding such products, providing market surveillance authorities with an interlocutor and performing specific tasks in a timely manner.

(39) Contact information of the economic operator, established in the Union and responsible for products falling under the scope of application of this Regulation should be indicated with the product in order to facilitate checks throughout the supply chain.

(40) Where economic operators or market surveillance authorities face a choice of various corrective measures, the most sustainable action resulting in the lowest environmental impact, such as the repair of the product, should be preferred, provided that it does not result in a lesser level of safety.

(41) Any economic operator that either places a product on the market under their own name or trademark or modifies a product in such a way that conformity with the requirements of this Regulation may be affected, should be considered to be the manufacturer and should assume the obligations of the manufacturer.

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

(43) When making products available on the market, economic operators should provide minimum information on product safety and traceability as part of the relevant offer. This should be without prejudice to the information requirements laid down by Directive 2011/83/EU of the European Parliament and of the Council[11], such as on the main characteristics of the goods, to the extent appropriate to the medium and to the goods.

(44) Ensuring product identification and the traceability of products throughout the entire supply chain helps to identify economic operators and to take effective corrective measures against dangerous products, such as targeted recalls. Product identification and traceability thus ensures that consumers and economic operators 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, if applicable, of the importer. Such traceability requirements could be made stricter for certain kinds of products. Manufacturers should also establish technical documentations regarding their products, which should contain the necessary information to prove that their product is safe.

(45) 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 close the gap between the two sets of provisions. For that purpose Articles 10 to 16, Articles 18 and 19 and Articles 21 to 24 of Regulation (EU) 2019/1020 should be applicable also to products covered by this Regulation.

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[11] 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).

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

(47) National authorities should be enabled to complement the traditional market surveillance activities focused on safety of products with market surveillance activities focusing on the internal conformity procedures set up by economic operators to ensure product safety. Market surveillance authorities should be able to require the manufacturer to indicate which other products - produced with the same procedure, or containing the same components considered to present a risk or that are part of the same production batch - are affected by the same risk.

(48) An exchange of information between Member States and the Commission concerning the implementation of this Regulation should be established on the basis of output indicators which would allow measuring and comparing Member States' effectiveness in implementing Union product safety legislation.

(49) There should be effective, speedy and accurate exchange of information concerning dangerous products.

(50) The Union rapid information system (RAPEX) has proved its effectiveness and efficiency. It enables corrective measures to be taken across the Union in relation to products that present a risk beyond the territory of a single Member State. It is opportune, though, to change the used abbreviated name from RAPEX to Safety Gate for greater clarity and better outreach to consumers. Safety Gate comprises a rapid alert system on dangerous non-food products whereby national authorities and the Commission can exchange information on such products, a web portal to inform the public (Safety Gate portal) and an interface to enable businesses to comply with their obligation to inform authorities and consumers of dangerous products (Safety Business Gateway).

(51) Member States should notify in the Safety Gate both compulsory and voluntary corrective measures that prevent, restrict or impose specific conditions on the possible marketing of a product because of a serious risk to the health and safety of consumers or, in case of products covered by Regulation (EU) No 2019/1020, also to other relevant public interests of the ~~end-users~~ **end users**.

(52) Under Article 34 of Regulation (EU) No 2019/1020, Member States authorities are to notify measures adopted against products covered by that Regulation, presenting a less than serious risk, through the information and communication system referred to in the same article, while corrective measures adopted against products covered by this Regulation presenting a less than serious risk should be notified in the Safety Gate. 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 adopted against products posing a risk are contained in the Safety Gate, allowing relevant information on dangerous products to be made available to the public through the Safety Gate portal. Member States are therefore encouraged to notify in the Safety Gate all corrective measures on products posing a risk to the health and safety of consumers.

(53) In case the information has to be notified in the information and communication system according to Regulation (EU) 2019/1020, there is the possibility, for such notifications, to be submitted directly in the Safety Gate or, to be generated from within the information and communication system for market surveillance provided for in Article 34 of Regulation (EU) 2019/1020. For this purpose, the Commission should maintain and further develop the interface that has been set up for the transfer of information between the information and communication system and the Safety Gate, in order to avoid double data entry and facilitate such transfer.

(54) The Commission should maintain and further develop the Safety Business Gateway web portal, enabling economic operators to comply with their obligations to inform market surveillance authorities and consumers of dangerous products they have placed or made available on the market. This tool should also enable economic operators to inform market surveillance authorities of accidents caused by products they have placed or 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.

(55) There might be cases where it is necessary to deal with a serious risk at the Union level where the risk cannot be contained satisfactorily by means of measures taken by the Member State concerned or by any other procedure under Union legislation. This could notably be the case of new emerging risks or those impacting vulnerable consumers. For that reason the Commission can adopt measures either on its own initiative or upon request of the Member States. Such measures should be adapted to the gravity and urgency of the situation. It is furthermore necessary to provide for an adequate mechanism whereby the Commission could adopt immediately applicable interim measures.

(56) The determination of the risk concerning a product and its level is based on a risk assessment performed by the relevant actors. Member States, in performing risk assessment, might reach different results as far as the presence of a risk or its level is concerned. This could jeopardise the correct functioning of the single market and the level playing field for both consumers and economic operators. An arbitration mechanism should therefore be made available to Member States, on a voluntary basis, which would allow the Commission, to provide an opinion on the issue in dispute.

(57) The Consumer Safety Network enhances the cooperation on product safety enforcement between Member States. In particular, it facilitates the activities of exchange of information, the organisation of joint market surveillance activities, the exchange of expertise and best practices. The Consumer Safety Network should be duly represented and participate in the coordination and cooperation activities of the Union Product Compliance Network provided for in Regulation (EU) 2019/1020 whenever coordination of activities falling under the scope of application of both Regulations is necessary to ensure their effectiveness.

(58) Market surveillance authorities might carry out joint activities with other authorities or organisations representing economic operators or end users, with a view to promoting safety of products and identifying dangerous products, including those that are offered for sale online. In doing so the market surveillance authorities and the Commission, as appropriate, should ensure that the choice of products and producers as well as the activities performed does not create situation which might distort competition or affect the objectivity, independence and impartiality of the parties.

(59) Simultaneous coordinated control actions (‘sweeps’) are specific enforcement actions that can further enhance product safety. In particular, sweeps should be conducted where market trends, consumer complaints or other indications suggest that certain product categories are often found to present a serious risk.

(60) The public interface of the Safety Gate, the Safety Gate portal, allows the general public, including consumers, economic operators and online marketplaces, to be informed about corrective measures taken against dangerous products present on the Union market. A separate section of the Safety Gate portal enables consumers to inform the Commission of products presenting a risk to consumer health and safety found in the market. Where relevant, the Commission should provide adequate follow-up, notably by transmitting such information to the concerned national authorities.

(61) In making available information on product safety to the public, professional secrecy, as referred to in Article 339 of the Treaty, should be protected in a way which is compatible with the need to ensure the effectiveness of market surveillance activities and of protection measures.

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

(63) A third of consumers continue using dangerous products despite seeing a recall notice, notably because recall notices are drafted in a complex way or minimise the risk at stake. The recall notice should therefore be clear, transparent and clearly describe the risk at stake, avoiding any terms, expressions or other elements that may decrease consumers' perception of risk. Consumers should also be able to get more information, if needed, via a toll-free telephone number or other interactive instrument.

(64) To encourage consumer response to recalls it is also important that the action required from consumers be as simple as possible and that the remedies offered be effective, cost-free and timely. Directive (EU) 2019/771 of the European Parliament and of the Council[12] provides the consumers with the contractual remedies for a lack of conformity of goods that existed at the time of delivery and became apparent within the liability period. The economic operator responsible for the recall should provide similar remedies to the consumer.

(65) In order to facilitate the effective and consistent application of the general safety requirement set out in this Regulation, it is important to make use of European standards covering certain products and risks in such a way that a product which conforms to such a European standard, the reference of which is published in the Official Journal of the European Union, is presumed to be in compliance with that requirement. **In case different risks or risk categories are covered by the same standard, the conformity of a product with the part of the standard covering the relevant risk or risk category would also give to the product itself presumption of safety as far as the relevant risk or risk category is concerned.**

[12] 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).

(66) Where the Commission identifies a need for a European standard ensuring compliance of certain products with the general safety requirement under this Regulation, it should apply the relevant provisions of Regulation (EU) No 1025/2012 of the European Parliament and of the Council[13] to request one or several European standardisation organisations to either draft or identify a standard which is suitable to ensure that products which conform to it are presumed to be safe.

(67) Certain provisions of Regulation (EU) 1025/2012 should be amended to take the specificities of this Regulation into account, and in particular the need to define the specific safety requirements under this Regulation before launching the request to the European standardisation organisation. **Standardisation requests issued by the Commission in accordance with Directive 2001/95/EC should be deemed standardisation requests issued in accordance with this Regulation.**

(68) Together with the adaptation of Regulation (EU) 1025/2012, a specific procedure for the adoption of the specific safety requirements with the assistance of the specialised Committee provided for by this Regulation should be introduced.

(69) European standards, the references of which have been published in accordance with Directive 2001/95/EC, should continue providing a presumption of conformity with the general safety requirement set out in this Regulation. ~~Standardisation requests issued by the Commission in accordance with Directive 2001/95/EC should be deemed standardisation requests issued in accordance with this Regulation.~~

(69a) In the absence of European standards, the law of the Member State where the product is made available on the market laying down health and safety requirements should comply with Union law, in particular Articles 34 and 36 of the TFEU.

[13] 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).

(70) The Union should be able to cooperate and to exchange information related to product safety with regulatory authorities of third countries or international organisations within the framework of agreements concluded between the Commission and third countries or international organisations. Such cooperation and exchange of information should respect confidentiality and personal data protection rules of the Union.

(71) In order to play a significant deterrent effect for economic operators and 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 online marketplace and to the type and gravity of the injury suffered by the consumer. Furthermore an homogenous level of penalties is important to ensure a level playing field, avoiding that economic operators or online marketplaces concentrate their activities in territories where the level of penalties is lower.

(72) When imposing penalties, due regard should be given to the nature, gravity and duration of the infringement in question. The imposition of penalties should be proportionate and should comply with Union and national law, including with applicable procedural safeguards and with the principles of the Charter of fundamental rights.

(73) In order to facilitate the more consistent application of penalties, common non-exhaustive and indicative criteria for the application of penalties should be included. Those criteria should include the duration or temporal effects of the infringement, as well as its nature and gravity, in particular the level of risk incurred by the consumer. Repeated infringement by the same perpetrator shows a propensity to commit such infringements and is therefore a significant indication of the gravity of the conduct and, accordingly, of the need to increase the level of the penalty to achieve effective deterrence. The financial benefits gained, or losses avoided, because of the infringement should be taken into account, if the relevant data are available. Other aggravating or mitigating factors applicable to the circumstances of the case should also be taken into account.

(74) In order to ensure more consistency, a list of those types of infringements that should be subject to penalties should be included.

(75) The deterrent effect of penalties should be reinforced by the possibility to publish the information related to the penalties imposed by Member States. Where these penalties are issued against natural persons or include personal data, they may be published in a manner that complies with the data protection requirements as set out in Regulation (EU) 2016/679 of the European Parliament and of the Council[14] and Regulation (EU) 2018/1725 of the European Parliament and of the Council[15]. The annual report on the penalties imposed by the Member States should contribute to the level playing field and to prevent repeated infringements. For reasons of legal certainty and in accordance with the principle of proportionality, it should be specified in which situations a publication should not take place. As far as natural persons are concerned, personal data should only be published in exceptional circumstances justified by the seriousness of the infringement, for instance when a penalty has been imposed to an economic operator whose name identifies a natural person and such economic operator has repeatedly failed to comply with the general product safety requirement.

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14 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).*

15 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).*

(76) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to adopt the specific safety requirements, to determine the output indicators on the basis of which Member States have to communicate data concerning the implementation of this Regulation, to adopt the modalities and procedures for the exchange of information regarding measures communicated through the Safety Gate and criteria to assess the level of risk, to take measures as regards the products presenting a serious risk, to adopt the modalities for the sending of information by consumers in the Safety Gate portal, to set out the requirements for registration of products for recall purposes and to adopt the template for a recall notice. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[16].

(77) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the health and safety of consumers, imperative grounds of urgency so require.

(78) In order to maintain a high level of health and safety of consumers, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in respect of the identification and traceability of products bearing a potential serious risk to health and safety. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[17]. 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.

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16 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).

17 OJ L 123, 12.5.2016, p. 1.

(79) Since the objectives of this Regulation, namely to ensure a consistent, high level of consumer health and safety protection while preserving the unity of the Single market, cannot be sufficiently achieved by the Member States given the need for a high degree of collaboration and coherent action between Member States' competent authorities and for a mechanism to quickly and efficiently exchange information on dangerous products in the Union but can rather, by reason of the Union-wide character of the problem, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(80) Any processing of personal data for the purpose of this Regulation should be in compliance with Regulations (EU) 2016/679 and (EU) 2018/1725. When consumers report a product in the Safety Gate, only those personal data will be stored that are necessary to report the dangerous product and for a period not exceeding five years after such data have been encoded. Manufacturers and importers should hold the register of consumer complaints only as long as it is necessary for the purpose of this Regulation. Manufacturers and importers, when they are natural persons should disclose their names to ensure that the consumer is able to identify the product for purpose of traceability.

(81) The European Data Protection Supervisor was consulted in accordance with Article 42 of Regulation (EU) 2018/1725 and delivered an opinion on XX XXXX.[18]

[18] …

HAVE ADOPTED THIS REGULATION:

CHAPTER I

General provisions

Article 1

Subject matter

This Regulation lays down essential rules on the safety of ~~consumer~~ products placed or made available on the market.

Article 2

Scope

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

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

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

   (a) Chapter II shall not apply insofar as the risks or categories of risks covered by Union harmonisation legislation are concerned;

   (b) Chapter III, Section 1, Chapters V and VII, Chapters IX to XI shall not apply.

2. This Regulation shall not apply to:

(a) medicinal products for human or veterinary use;

(b) food;

(c) feed;

(d) living plants and animals, genetically modified organisms and genetically modified microorganisms in contained use, as well as products of plants and animals relating directly to their future reproduction;

(e) animal by-products and derived products;

(f) plant protection products;

(g) equipment on which consumers ~~ride or~~ travel **but** which is ~~operated~~ **driven** by a service provider within the context of a service provided to consumers;

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

(i) **works of art, collectors' pieces and** antiques.

3. This Regulation shall apply to products placed or made available on the market whether new, used, repaired or reconditioned. It shall not apply to products to be repaired or reconditioned prior to being used where those products are made available on the market as such.

4. This Regulation is without prejudice to the rules laid down by Union law on consumer protection.

5. This Regulation shall be applied taking due account of the precautionary principle.

Article 3

Definitions

For the purposes of this Regulation the following definitions apply:

1. ‘product’ means any **tangible or non-tangible** item, ~~interconnected or not to other items, supplied~~ **placed** or made available **on the market**, whether for consideration or not, ~~in the course of a commercial activity~~ including in the context of providing a service – which is intended for consumers or can, under reasonably foreseeable conditions, 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 ~~or misuse~~, including the actual duration of use, does not present any risk or only the minimum risks compatible with the product's use, considered acceptable and consistent with a high level of protection of health and safety of consumers;

3. ‘dangerous product’ means any product which does not conform to the definition of ‘safe product’;

4. ‘risk’ means the combination of the probability of an occurrence of a hazard causing harm and the degree of severity of that harm;

5. ‘serious risk’ means a risk for which, based on a risk assessment and taking into account the normal and foreseeable use of the product, the combination of the probability of occurrence of a hazard causing harm and the degree of severity of the harm is considered to require rapid intervention by the market surveillance authorities, including cases where the effects of the risk are not immediate;

6. ‘making available on the market’ means any supply of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

7. ‘placing on the market’ means the first making available of a product on the Union market;

8. ‘manufacturer’ means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under its name or trademark;

9. ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his or her behalf in relation to specified tasks **with regard to the manufacturer’s obligations under this Regulation**;

10. ‘importer’ means any natural or legal person established within the Union who places a product from a third country on the Union market;

11. ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;

12. ‘fulfilment service provider’ means any natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved, excluding postal services as defined in Article 2, point 1 of Directive 97/67/EC of the European Parliament and of the Council[19], parcel delivery services as defined in Article 2, point 2 of Regulation (EU) 2018/644 of the European Parliament and of the Council[20], and any other postal services or freight transport services;

13. ‘economic operator’ means the manufacturer, the authori0sed representative, the importer, the distributor, the fulfilment service provider or any other natural or legal person who is subject to obligations in relation to the manufacture of products, making them available on the market in accordance with this Regulation;

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19 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).

20 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. ‘online marketplace’ means a provider of an intermediary service using software, including a website, part of a website or an application, operated by or on behalf of a trader, which allows consumers to conclude distance contracts with other traders or consumers for the sale of products covered by this Regulation;

15. ‘online interface’ means any software, including a website, part of a website or an application, that is operated by or on behalf of an economic operator, and which serves to give end users access to the economic operator's products;

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

16. ‘end user’ means any natural or legal person residing or established in the Union, to whom a product has been made available either as a consumer outside of any trade, business, craft or profession or as a professional end user in the course of its industrial or professional activities;

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

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

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

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

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

22. ‘market surveillance authority’ means an authority designated by a Member State under Article 10 of Regulation (EU) 2019/1020 **or referred to in Article 21 of this Regulation** as responsible for organising and carrying out market surveillance in the territory of that Member State;

23. ‘recall’ means any measure aimed at achieving the return of a product that has already been made available to the ~~consumer~~ **end user**;

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

25. ‘Union harmonisation legislation’ means Union legislation listed in Annex I to Regulation (EU) 2019/1020 and any other Union legislation harmonising the conditions for the marketing of products to which that Regulation applies.

Article 4

Distance sales

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

~~2. For the purpose of determining whether an offer is targeted at consumers in the Union, the following non-exhaustive criteria shall be taken into account:~~

~~(a) the use of an official language or currency of the Member States,~~

~~(b) a domain name registered in one of the Member States,~~

~~(c) the geographical areas to which the products can be dispatched.~~

CHAPTER II

Safety requirements

Article 5

General safety requirement

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

~~*Article 6*~~ *[moved to new Art. 7a]*

~~**Presumption of safety**~~

~~1. For the purpose of this Regulation, a product shall be presumed to be in conformity with the general safety requirement laid down in Article 5 in the following cases:~~

~~(a) if it conforms to relevant European standards or parts thereof as far as the risks and risk categories covered 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) 1025/2012;~~

~~(b) in the absence of European standards referred to in point (a), as regards the risks covered by health and safety requirements laid down in the law of the Member State where the product is made available on the market, if it conforms to such national requirements.~~

~~2. The Commission shall adopt implementing acts determining the specific safety requirements necessary to ensure that products which conform to the European standards satisfy the general safety requirement laid down in Article 5. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 42(3).~~

~~3. However, presumption of safety under paragraph 1 shall not prevent market surveillance authorities from taking action under this Regulation where there is evidence that, despite such conformity, the product is dangerous.~~

Article 7

Aspects for assessing the safety of products

1. ~~Where the presumption of safety laid down in Article 5 does not apply, the~~ **The** following aspects shall be taken into account in particular when assessing whether a product is safe:

(a) the characteristics of the product, including its design, technical features, composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;

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

(c) the effect that other products might have on the product to be assessed, including the effect of non-embedded items that are meant to determine, change or complete the way ~~another product falling under the scope of this Regulation~~ **the product to be assessed** works~~, which have to be taken into consideration in assessing the safety of that other product~~;

(d) the presentation of the product, the labelling, any warnings and instructions for its items

(e) the categories of consumers at risk when using the product, in particular vulnerable consumers such as children, older people and persons with disabilities;

(f) the appearance of the product and in particular 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;

(fa) the appearance of the product where it encourages consumers to use it in a way different from what it was designed for;

(g) the fact that although not designed or not intended for use by children, the product resembles an object commonly recognized as appealing to or intended for use by children, because of its design, packaging and characteristics;

(h) the appropriate cybersecurity features necessary to protect the product against external influences, including malicious thi rd parties, when such an influence might have an impact on the safety of the product;

(i) the evolving, learning and predictive functionalities of a product.

~~2. The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product not to be safe.~~

3. For the purpose of paragraph 1, **and without prejudice to the application of Article 7a,** when assessing whether a product is safe, the following elements, when available, shall be taken into account, in particular:

(a) European standards ~~other than those the references of which have been published in the Official Journal of the European Union in accordance with Article 10(7) of Regulation (EU) 1025/2012~~;

(b) international standards;

(c) international agreements;

(d) voluntary certification schemes or similar third-party conformity assessment frameworks, in particular those conceived to support Union legislation;

(e) ~~Commission~~ recommendations or guidelines on product safety assessment **from the Commission or other Union institutions or agencies**;

(f) national standards drawn up in ~~the~~ **a** Member State ~~in which the product is made available~~;

(g) the state of the art and technology, including the opinion of recognized scientific bodies and expert committees;

(h) product safety codes of good practice in force in the sector concerned;

(i) reasonable consumer expectations concerning safety;

(j) safety requirements adopted in accordance with Article ~~6~~ **7a**(2).

Article 7a *[moved from Art. 6, with changes]*

Presumption of safety

1. For the purpose of this Regulation, a product shall be presumed to be in conformity with the general safety requirement laid down in Article 5 in the following cases:

(a) if it conforms to relevant European standards drawn up in support of this Regulation or parts thereof as far as the risks and risk categories covered 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) 1025/2012;

(b) in the absence of the European standards referred to in point (a), if the product conforms to national requirements, as regards the risks covered by health and safety requirements laid down in the law of the Member State it is made available on the market, provided that such law is in compliance with Union law.

2. The Commission shall adopt implementing acts determining the specific safety requirements to be covered by European standards in order to ensure that products which conform to these European standards satisfy the general safety requirement laid down in Article 5. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 42(3).

3. However, presumption of safety under paragraph 1 shall not prevent market surveillance authorities from taking action under this Regulation where, despite such conformity, there is reliable documented information that the product is dangerous.

CHAPTER III

Obligations of economic operators

Section 1

Article 8

Obligations of manufacturers

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

2. Manufacturers shall investigate the complaints received that concern products they made available on the market, and which have been identified as dangerous by the complainant, and shall keep a register of these complaints as well as of product recalls.

Manufacturers shall make publicly available to consumers, communication channels such as telephone number, electronic address or dedicated section of their website, allowing the consumers to file complaints and to inform them of any accident or safety issue they have experienced with the product.

Personal data stored in the register of complaints shall only be those personal data that are necessary for the manufacturer to investigate the complaint about an alleged dangerous product. Such data shall only be kept as long as it is necessary for the purpose of investigation and no longer than five years after they have been encoded.

3. Manufacturers shall keep distributors, importers and online marketplaces in the concerned supply chain informed of any safety issue that they have identified.

4. Manufacturers shall draw up technical documentation of the product. The technical documentation shall contain, as appropriate:

(a) a general description of the product and its essential properties relevant for assessing the product's safety;

(b) an analysis of the possible risks related to the product and the solutions adopted to eliminate or mitigate such risks, including the outcome of any tests conducted by the manufacturer or by another party on their behalf;

(c) the list of the European standards referred to in Article 6(1) point a, or the other elements referred to in Article 7(3), applied to meet the general safety requirement laid down in Article 5.

Where any of the European standards, health and safety requirements or elements referred to in Article 7(3) have been only partly applied, the parts which have been applied shall be identified.

5. Manufacturers shall keep the technical documentation, for a period of ten years after the product has been placed on the market and make it available to the market surveillance authorities, upon request.

6. Manufacturers shall ensure that their products bear a type, batch or serial number or other element allowing the identification of the product which is easily visible and legible for consumers, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product.

7. Manufacturers shall indicate their name, registered trade name or registered trade mark and the postal and electronic address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product. The address shall indicate a single contact point at which the manufacturer can be contacted.

8. Manufacturers shall ensure that their product is accompanied by instructions and safety information in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available. This requirement shall not apply where the product can be used safely and as intended by the manufacturer without such instructions and safety information.

9. Manufacturers shall ensure that procedures are in place for series production to remain in conmformity with the general safety requirement laid down in Article 5.

10. Manufacturers who consider or have reason to believe, on the basis of the information in their possession, that a product which they have placed on the market is not safe, shall immediately take the corrective measures necessary to bring the product into conformity, including a withdrawal or recall, as appropriate.

11. Manufacturers shall, via the Safety Business Gateway referred to in Article 25, immediately alert consumers of the risk to their health and safety presented by a product they manufacture and immediately inform the market surveillance authorities of the Member States in which the product has been made available to that effect, giving details, in particular, of the risk to health and safety of consumers and of any corrective measure already taken.

Article 9

Obligations of authorised representatives

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

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to perform at least the following tasks:

   (a) provide a market surveillance authority, upon its reasoned request, with all information and documentation necessary to demonstrate the safety of the product in an official language which can be understood by that authority;

   (b) where they have a reason to believe that a product in question presents a risk, inform the manufacturer;

   (c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by products covered by their mandate.

Article 10

Obligations of importers

1. Before placing a product on the market importers shall ensure that the product is compliant with the general safety requirement laid down in Article 5 and that the manufacturer has complied with the requirements set out in Article 8 (4), (6) and (7).

2. Where an importer considers or has reason to believe that a product is not in conformity with Article 5 and Article 8(4), (6) and (7), he or she shall not place the product on the market until it has been brought into conformity. Furthermore, where the product is not safe, the importer shall inform the manufacturer and ensure that the market surveillance authorities are informed.

3. Importers shall indicate their name, registered trade name or registered trade mark, the postal and electronic address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.

4. Importers shall ensure that the product they imported is accompanied by instructions and safety information in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available, except where the product can be used safely and as intended by the manufacturer without such instructions and safety information.

5. Importers shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardize its conformity with the general safety requirement laid down in Article 5 and its conformity with Article 8 (6) and (7).

6. Importers shall investigate complaints related to products they made available on the market and file these complaints, as well as products recalls, in the register referred to in Article 8(2), first subparagraph, or in their own register. Importers shall keep the manufacturer and distributors informed of the investigation performed and of the results of the investigation.

   Importers shall ensure that the communication channels referred to in Article 8(2), second subparagraph, are available to consumers allowing them to present complaints and communicate any accident or safety issue they have experienced with the product. If such channels are not available the importer shall provide for them.

   Personal data stored in the register of complaints shall only be those personal data that are necessary for the importer to investigate the complaint about an alleged dangerous product. Such data shall only be kept as long as it is necessary for the purpose of investigation and no longer than five years after they have been encoded.

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

8. Importers who consider or have reason to believe, on the basis of the information in their possession, that a product which they have placed on the market is not safe shall immediately inform the manufacturer and ensure that the corrective measures necessary to bring the product into conformity are adopted including withdrawal or recall, as appropriate. In case such measures have not been adopted, the importer shall adopt them. Importers shall ensure that, through the Safety Business Gateway referred to in Article 25, consumers are immediately and effectively alerted of the risk where applicable and that market surveillance authorities of the Member States in which they made the product available to that effect be immediately informed, giving details, in particular, of the risk to health and safety of consumers and of any corrective measure already taken.

9. Importers shall keep the technical documentation referred to in Article 8(4) for a period of 10 years after they have placed the product on the market and make it available to the market surveillance authorities, upon request.

Article 11

Obligations of distributors

1. Before making a product available on the market, distributors shall verify that the manufacturer and the importer have complied with the requirements set out in Article 8(6), (7) and (8) and Article 10(3) and (4), as applicable.

2. Distributors shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardize its conformity with the general safety requirement laid down in Article 5 and its conformity with Article 8(6), (7) and (8) and Article 10(3) and (4), as applicable.

3. Distributors who consider or have reason to believe, on the basis of the information in their possession, that a product is not in conformity with the provisions referred to in paragraph 2, shall not make the product available on the market until it has been brought into conformity. Furthermore, where the product is not safe, the distributor shall immediately inform the manufacturer or the importer, as applicable, to that effect and shall make sure that, through the Safety Business Gateway referred to in Article 25, the market surveillance authorities are informed.

4. Distributors who consider or have reason to believe, on the basis of the information in their possession, that a product which they have made available on the market is not safe or is not in conformity with Article 8(6), (7) and (8) and Article 10(3) and (4), as applicable, shall ensure that the corrective measures necessary to bring the product into conformity are adopted, including withdrawal or recall, as appropriate. Furthermore, where the product is not safe, distributors shall immediately inform the manufacturer or the importer, as applicable, to that effect and shall make sure that, through the Safety Business Gateway referred to in Article 25, the market surveillance authorities of the Member State in which they made the product available to that effect are informed giving details, in particular, of the risk to health and safety and of any corrective measure taken.

Article 12

Cases in which obligations of manufacturers apply to other economic operators

1. A natural or legal person, other than the manufacturer, that substantially modifies the product, shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 8 for the part of the product affected by the modification or for the entire product if the substantial modification has an impact on its safety.

2. A modification shall be deemed to be substantial where the three following criteria are met:

(a) the modification changes the intended functions, type or performance of 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 or the level of risk has increased because of the modification;

(c) the changes have not been made by the consumer for their own use.

Article 13

Internal processes for product safety

The economic operators shall ensure that they have internal processes for product safety in place, allowing them to respect the general safety requirement laid down in Article 5.

Article 14

Cooperation of economic operators with market surveillance authorities

1. Economic operators shall cooperate with market surveillance authorities regarding actions which could eliminate or mitigate risks that are presented by products made available on the market by those operators.

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

(a) a full description of the risk presented by the product;

(b) a description of any corrective measure undertaken to address the risk.

3. On request, the economic operators shall also identify and communicate the following information:

(a) any economic operator who has supplied them with the product;

(b) any economic operator to whom they have supplied the product.

4. Economic operators shall be able to present the information referred to in paragraph 2 for a period of ten years after they have been supplied with the product and for a period of ten years after they have supplied the product, where relevant.

5. Economic operators shall ensure that the corrective measure undertaken is effective in eliminating or mitigating the risks. Market surveillance authorities may request the economic operators to submit regular progress reports and decide whether or when the corrective measure can be considered completed.

Article 15

Responsible person for products placed on the Union market

1. Article 4(1), (2) and (3) of Regulation (EU) 2019/1020 shall also apply to products covered by this Regulation. For the purposes of this Regulation, references to "Union harmonisation legislation" in Article 4(1), (2) and (3) of Regulation (EU) 2019/1020 shall be read as "Regulation […]".

2. In addition to the tasks referred to in Article 4(3) of Regulation (EU) 2019/1020, the economic operator referred to in Article 4(1) of Regulation (EU) 2019/1020 shall periodically carry out sample testing of randomly chosen products made available on the market. When the products made available on the market have been subject to a Commission decision adopted under Article 26(1) of this Regulation, the economic operator referred to in Article 4(1) of Regulation (EU) 2019/1020 shall carry out, at least once a year, for the entire duration of the decision, representative sample testing of products made available on the market chosen under the control of a judicial officer or any qualified person designated by the Member State where the economic operator is situated.

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 Article 4(1) of Regulation (EU) 2019/1020 shall be indicated on the product or on its packaging, the parcel or an accompanying document.

Article 16

Information to economic operators

Member States shall put in place procedures for providing economic operators, at their request and free of charge, with information with respect to the implementation of this Regulation.

Article 17

Traceability of products

1. For certain products, categories or groups of products, which are susceptible to bear a serious risk to health and safety of consumers, based on accidents registered in the Safety Business Gateway, the Safety Gate statistics, the results of the joint activities on product safety and other relevant indicators or evidence, the Commission may require economic operators who place and make available those products on the market to establish or adhere to a system of traceability.

2. The system of traceability shall consist in the collection and storage of data, including by electronic means, enabling the identification of the product, its components or of the economic operators involved in its supply chain, as well as in modalities to display and to access that data, including placement of a data carrier on the product, its packaging or accompanying documents.

3. The Commission is empowered to adopt delegated acts in accordance with Article 41 to supplement this Regulation by:

(a) determining the products, categories or groups of products or components susceptible to bear a serious risk to health and safety of persons as referred to in paragraph 1. The Commission shall state in the delegated acts concerned if it has used the risk analysis methodology provided for in Commission Decision (EU) 2019/417[21] or, if that methodology is not appropriate for the product concerned, it shall give a detailed description of the methodology used;

(b) specifying the type of data, which economic operators shall collect and store by means of the traceability system referred to in paragraph 2;

(c) 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.

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

(a) the cost-effectiveness of the measures, including their impact on businesses, in particular small and medium-sized enterprises;

(b) the compatibility with traceability systems available at Union or at international level.

[21] 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).*

Section 2

Article 18

Obligations of economic operators in case of distance sales

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

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

(b) in case the manufacturer is not established in the Union, the name, address, telephone number and electronic address of the responsible person within the meaning of Article 15(1);

(c) information to identify the product, including its type and, when available, batch or serial number and any other product identifier;

(d) any warning or safety information that is to be affixed on the product or to accompany it in accordance with this Regulation or the applicable Union harmonisation legislation in a language which can be easily understood by consumers.

Article 19

Obligations of economic operators in case of accidents or safety issues related to products

1. The manufacturer shall ensure that, through the Safety Business Gateway referred to in Article 25, an accident caused by a product placed or made available on the market is notified, within two working days 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. 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 inform the manufacturer, which can instruct the importer or one of the distributors to proceed to the notification.

CHAPTER IV

Online marketplaces

Article 20

Specific obligations of online marketplaces related to product safety

1. 1. Online marketplaces shall establish a single contact point allowing for direct communication with Member States' market surveillance authorities in relation to product safety issues, in particular for orders concerning offers of dangerous products.

   Online marketplaces shall register with the Safety Gate portal and indicate on the portal the information concerning their single contact point.

2. As far as powers conferred by Member States in accordance to Article 14 of Regulation (EU) 2019/1020 are concerned, Member States shall confer on their market surveillance authorities the power, for all products covered by this Regulation, to order an online marketplace to remove specific illegal content referring to a dangerous product from its online interface, to disable access to it or to display an explicit warning to end users when they access it. Such orders shall contain a statement of reasons and specify one or more exact uniform resource locators and, where necessary, additional information enabling the identification of the illegal content concerned. They may be transmitted by means of the Safety Gate portal.

Online marketplaces shall take the necessary measures to receive and process the orders issued in accordance with this paragraph. They shall act upon receipt of the order issued without undue delay, and in any event within two working days in the Member State where the online marketplace operates, from receipt of the order. They shall inform the issuing market surveillance authority of the effect given to the order by using the contacts of the market surveillance authority published in the Safety Gate.

3. Online marketplaces shall take into account regular information on dangerous products notified by the market surveillance authorities in line with Article 24, received via the Safety Gate portal, for the purpose of applying their voluntary measures aimed at detecting, identifying, removing or disabling access to the illegal content referring to dangerous products offered on their marketplace, where applicable. They shall inform the authority that made the notification to the Safety Gate of any action taken by using the contacts of the market surveillance authority published in the Safety Gate.

4. Online marketplaces shall give an appropriate answer without undue delay, and in any event within five working days, in the Member State where the online marketplace operates, to notices related to product safety issues and dangerous products received in accordance with [Article 14] of Regulation (EU) […/…] on a Single Market for Digital Services (Digital Service Act) and amending Directive 2000/31/EC.

5. For the purpose of the requirements of Article 22(7) of Regulation (EU) […/…] on a Single Market for Digital Services (Digital Services Act) and amending Directive 2000/31/EC, online marketplaces shall design and organise their online interface in a way that enables traders to provide the following information for each product offered and ensures that it is displayed or otherwise made easily accessible by consumers on the product listing:

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

(b) where the manufacturer is not established in the Union, the name, address, telephone number and electronic address of the responsible person within the meaning of Article 15 (1);

(c) information to identify the product, including its type and, when available, batch or serial number and any other product identifier;

(d) any warning or safety information that is to be affixed on the product or to accompany it in accordance with this Regulation or the applicable Union harmonisation legislation in a language which can be easily understood by consumers.

6. Online marketplaces shall cooperate with the market surveillance authorities 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 for sale online through their services. That cooperation shall include in particular:

(a) cooperating to ensure effective product recalls, including by abstaining from putting obstacles to product recalls;

(b) informing the market surveillance authorities of any action taken;

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

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

(e) upon request of the market surveillance authorities, when online marketplaces or online sellers have put in place technical obstacles to the extraction of data from their online interfaces (data scraping), allowing to scrape such data for product safety purposes based on the identification parameters provided by the requesting market surveillance authorities.

CHAPTER V

Market surveillance and implementation

Article 21

Market Surveillance

1. Articles 10 to 16, Articles 18 and 19 and Articles 21 to 24 of Regulation (EU) 2019/1020 shall apply to products covered by this Regulation.

2. For the purpose of this Regulation, Regulation (EU) 2019/1020 shall be applied as follows:

(a) references to 'Union harmonisation legislation'**, 'applicable Union harmonisation legislation', 'this Regulation and for the application of Union harmonisation legislation', 'the relevant Union harmonisation legislation' and 'Union harmonisation legislation or this Regulation'** in Articles 10 to 16, Articles 18 and 19 and Articles 21 to 24 of Regulation (EU) 2019/1020 shall be read as references to 'this Regulation';

(b) reference to 'that legislation and this Regulation' in Article 11(1) point b of Regulation (EU) 2019/1020 shall be read as **reference to 'this** Regulation~~[…]~~';

(c) references to ‘Network’ in Articles 10 to 16, Articles 18 and 19 and Articles 21 to 24 of Regulation (EU) 2019/1020 shall be read as references to ‘Network and Consumer Safety Network referred to in Article 28 of this Regulation’;

(d) references to ‘non-compliance’**, ‘non-compliances’, ‘non-compliant’ and ‘non-compliant products’** in Articles 10 to 16, Articles 18 and 19 and Articles 21 to 24 of Regulation (EU) 2019/1020 shall be read as ~~reference~~ **references** to ‘failure to comply with this Regulation’;

(da) references to ‘information and communication system referred to in Article 34’ in Article 16(6) and (7) of Regulation (EU) 2019/1020 shall be read as references to ‘Safety Gate according to Article 24 of this Regulation’;

(e) the reference to ‘Article 41’ in Article 14(4), point (i) of Regulation (EU) 2019/1020 shall be read as reference to ‘Article 40 of this Regulation’:

(f) the reference to ‘Article 20’ in Article 19(1) of Regulation (EU) 2019/1020 shall be read as reference to ‘Article 24 of this Regulation’.

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

4. Market surveillance authorities may set up schemes focusing on control of internal processes for product safety set up by economic operators according to Article 13.

Article 22

Implementation

1. Member States shall communicate to the Commission, ~~once a year~~ **every two years**, data concerning the implementation of this Regulation.

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

CHAPTER VI

Safety Gate rapid alert system

Article 23

Safety Gate

1. The Commission shall further develop and maintain a rapid alert system for the exchange of information on corrective measures concerning dangerous products ('the Safety Gate').

2. The Commission and the Member States shall have access to the Safety Gate. For that purpose, each Member State shall designate a single national contact point which shall perform the tasks provided for in Article 24(1) to (6).

Article 24

Notification through the Safety Gate of products presenting a risk

1. Member States shall notify in the Safety Gate corrective measures taken by their authorities or by economic operators:

   (a) on the basis of provisions of this Regulation in relation to products presenting a risk to the health and safety of consumers;

   (b) on the basis of Regulation (EU) 2019/1020 in relation to products presenting a serious risk, in accordance with Article 20 of Regulation (EU) 2019/1020.

2. Member States may notify in the Safety Gate corrective measures taken by their authorities or by economic operators on the basis of provisions of Union harmonisation legislation and Regulation (EU) 2019/1020 in relation to products presenting a less than serious risk.

   The notification shall be submitted in the Safety Gate within two working days from the adoption of the corrective measure.

3. On receiving a notification, the Commission shall check whether it complies with this Article and with the requirements related to the operation of Safety Gate defined by the Commission on the basis of paragraph 7, and shall transmit it to the other Member States if the requirements are complied with.

4. Member States shall notify in the Safety Gate without delay any update, modification or withdrawal of the corrective measures referred in paragraph 1.

5. Where a Member State notifies corrective measures taken in relation to products presenting a serious risk, the other Member States shall notify in the Safety Gate the measures and actions taken subsequently in relation to the same products and any other relevant information, including the results of any tests or analyses carried out, within two working days from the adoption of the measures or actions.

6. If the Commission identifies products which are likely to present a serious risk and for which Member States have not submitted a notification in the Safety Gate, it shall inform the Member States. Member States shall undertake the appropriate verifications and, if they adopt measures, notify them in the Safety Gate in accordance with paragraph 1.

7. The Commission shall develop an interface between the information and communication system referred to in Article 34 of Regulation (EU) 2019/1020 and the Safety Gate, in order to avoid double data entry and enable a draft Safety Gate notification to be triggered from that information and communication system.

8. The Commission shall adopt implementing acts specifying the implementation of this Article, and in particular the access to the system, the operation of the system, the information to be entered in the system, the requirements notifications must meet, and criteria to assess the level of risk. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 42(3).

Article 25

Safety Business Gateway

1. The Commission shall maintain a web portal enabling the economic operators to provide market surveillance authorities and consumers with the information referred to in Articles 8(11), 9(2) point c), 10(8), 11(3), 11(4) and Article 19.

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

CHAPTER VII

Commission role and enforcement coordination

Article 26

Union action against products presenting a serious risk

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

   (a) it emerges from prior consultations with the Member States that they differ significantly on the approach adopted or to be adopted to deal with the risk; and;

(b) the risk cannot be dealt with, in view of the nature of the safety issue posed by the product, category or group of products, in a manner compatible with the degree of gravity or urgency of the case, under other procedures laid down by the specific Union legislation applicable to the products concerned; and

(c) the risk can be eliminated effectively only by adopting appropriate measures applicable at Union level, in order to ensure a consistent and high level of protection of the health and safety of consumers and the proper functioning of the internal market.

Those measures may include measures prohibiting, suspending or restricting the placing or making available on the market of such products or laying down special conditions for their marketing, in order to ensure a high level of consumer safety protection.

In those implementing acts, the Commission shall lay down the appropriate control measures to be taken by Member States to ensure their effective implementation.

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

3. On duly justified imperative grounds of urgency relating to the health and safety of consumers the Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 42(4).

4. The export from the Union of a product that has been prohibited to be placed or made available on the Union market pursuant to a measure adopted in accordance with paragraph 1 or 3 shall be prohibited, unless the measure expressly so permits.

5. Any Member State may submit a substantiated request to the Commission to examine the need for the adoption of a measure referred to in paragraph 1 or 3.

Article 27

Arbitration mechanism

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

2. Where market surveillance authorities in other Member States reach a different conclusion in terms of identification or level of the risk on the basis of their own investigation and risk assessment, the Member States concerned may request the Commission to arbitrate. In that case, the Commission shall invite all Member States to express a recommendation.

3. Taking into account the recommendations referred to in paragraph 2, the Commission shall adopt an opinion on the identification or on the level of the risk of the relevant product as appropriate

4. The opinion shall be taken into due account by the Member States.

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

Article 28

Consumer Safety Network

1. A European network of the authorities of the Member States competent for product safety (‘Consumer Safety Network’) shall be established.

2. The Commission shall promote and take part in the operation of the Consumer Safety Network, in particular in the form of administrative cooperation.

3. The objective of that Consumer Safety Network shall be, in particular, to facilitate:

(a) the exchange of information on risk assessments, dangerous products, test methods and results, recent scientific developments as well as other aspects relevant for control activities;

(b) the establishment and execution of joint surveillance and testing projects;

(c) the exchange of expertise and best practices and cooperation in training activities;

(d) improved cooperation at EU level with regard to the tracing, withdrawal and recall of dangerous products;

(e) enhanced cooperation on product safety enforcement between Member States, in particular to facilitate the activities referred to in Article 30~~.~~**;**

(ea) the implementation of this Regulation.

4. The Consumer Safety Network shall coordinate its action with the other existing Union activities.

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

Article 29

Joint activities on product safety

1. In the framework of the activities referred to in Article 28(3), point (b), market surveillance authorities may agree with other relevant authorities or with organisations representing economic operators or consumers to carry out activities aimed at ensuring safety and protection of consumers health with respect to specific categories of products placed or made available on the market, in particular categories of products that are often found to present a serious risk.

2. The market surveillance authorities and the Commission, where applicable, shall ensure that the agreement to carry out activities does not lead to unfair competition between economic operators and does not affect the objectivity, independence and impartiality of the parties to the agreement.

3. A market surveillance authority may use any information resulting from the activities carried out as part of any investigation regarding the safety of products that it undertakes.

4. The market surveillance authority concerned and the Commission where applicable shall make the agreement on joint activities, including the names of the parties involved, available to the public.

Article 30

Sweeps

1. Market surveillance authorities may decide to conduct simultaneous coordinated control actions (“sweeps”) of particular product categories to check compliance with or to detect infringements to this Regulation.

2. Unless otherwise agreed upon by the market surveillance authorities concerned, sweeps shall be coordinated by the Commission. The coordinator of the sweep may, where appropriate, make the aggregated results publicly available.

3. When conducting sweeps, the market surveillance authorities involved may use the investigation powers set out in Chapter V and any other powers conferred upon them by national law.

4. Market surveillance authorities may invite Commission officials, and other accompanying persons authorised by the Commission, to participate in sweeps.

CHAPTER VIII

Right to information and remedy

Article 31

Information between public authorities and consumers

1. Information available to the authorities of the Member States or to the Commission relating to measures on products presenting risks to consumer health and safety shall in general be made available to the public, in accordance with the requirements of transparency and without prejudice to the restrictions required for monitoring and investigation activities. In particular, the public shall have access to information on product identification, the nature of the risk and the measures taken. This information shall be provided in accessible formats for persons with disabilities.

2. Member States and the Commission shall take the necessary steps to ensure that their officials and agents are required not to disclose information obtained for the purposes of this Regulation which, by its nature, is covered by professional secrecy in duly justified cases, except for information relating to the safety properties of products which must be made public in order to protect consumers.

3. Protection of professional secrecy shall not prevent the dissemination to the competent authorities of Member States 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.

4. Member States shall give consumers and other interested parties the opportunity to submit complaints to the competent authorities on product safety and on surveillance and control activities and these complaints shall be followed up as appropriate.

Article 32

Safety Gate portal

1. For the purpose of Article 31(1) and Article 19, the Commission shall maintain a Safety Gate portal, providing the general public with free access to selected information notified in accordance with Article 24.

2. Consumers shall have the possibility to inform the Commission of products presenting a risk to consumer health and safety through a separate section of the Safety Gate portal. The Commission shall take in due consideration the information received and ensure follow up, where appropriate.

3. The Commission, by means of an implementing act, shall adopt the modalities for the sending of information by consumers in accordance with paragraph 2, as well as for the transmission of such information to the concerned national authorities for possible follow up. This implementing act shall be adopted in accordance with the examination procedure referred to in Article 42(3).

Article 33

Information from economic operators to consumers

1. In case of a recall or where certain information has to be brought to the attention of consumers to ensure the safe use of a product ('safety warning'), economic operators, in accordance with their respective obligations as provided for in Articles 8, 9, 10 and 11, shall directly notify all affected consumers that they can identify. Economic operators who collect their customers' personal data shall make use of this information for recalls and safety warnings.

2. Where economic operators have product registration systems or customer loyalty programs in place for purposes other than contacting their customers with safety information, they shall offer the possibility to their customers to provide separate contact details only for safety purposes. The personal data collected for that purpose shall be limited to the necessary minimum and may only be used to contact consumers in case of a recall or safety warning.

3. The Commission, by means of implementing acts, shall set out requirements for registration of products or specific categories of products. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 42(3).

4. If not all affected consumers can be contacted directly, economic operators, in accordance with their respective responsibilities, shall disseminate a recall notice or safety warning through other appropriate channels, ensuring the widest possible reach including, where available: the company's website, social media channels, newsletters and retail outlets and, as appropriate, announcements in mass media and other communication channels. Information shall be accessible to consumers with disabilities.

Article 34

Recall notice

1. Where information on a recall is provided to consumers in a written form, in accordance with Articles 33(1) and (4), it shall take the form of a recall notice.

2. A recall notice shall be available in the language(s) of the Member State(s) where the product has been put on the market and include the following elements:

   (a) headline ‘Product safety recall’;

   (b) clear description of the recalled product, including:

      (i) photograph, name and brand of the product;

      (ii) product identification numbers, such as batch or serial number, and, if applicable, graphical indication of where to find them on the product;

      (iii) information on when and where the product was sold, if available.

   (c) clear description of the hazard associated with the recalled product, avoiding any elements that may decrease consumers’ perception of risk, including terms and expressions such as “voluntary”, “precautionary”, “discretionary”, “in rare/specific situations” as well as indicating that there have been no reported accidents;

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

   (e) clear description of the remedy available to consumers if appropriate;

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

   (g) an encouragement to further share information about the recall, if appropriate.

3. The Commission, by means of implementing acts, shall set out the template for a recall notice, taking into account scientific and market developments. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 42(2).

Article 35

Right to remedy

1. Without prejudice to Directive (EU) 2019/771, in the case of a recall, the economic operator responsible for the recall shall offer to the consumer an effective, cost-free and timely remedy. That remedy shall consist of at least one of the following:

   (a) repair of the recalled product;

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

   (c) refund of the value of the recalled product.

2. Repair, disposal or destruction of the product by consumers shall only be considered an effective remedy where it can be carried out easily and safely by the consumer. In such cases, the economic operator responsible for the recall shall provide consumers with the necessary instructions and/or, in the case of self-repair, free replacement parts or software updates.

3. The remedy shall not entail significant inconvenience for the consumer. The consumer shall not bear the costs of shipping or otherwise returning the product. For products that by their nature are not portable, the economic operator shall arrange for the collection of the product.

CHAPTER IX

International cooperation

Article 36

International cooperation

1. The Commission may cooperate, including through the exchange of information, with third countries or international organisations in the field of application of this Regulation, such as:

   (a) enforcement activities and measures related to safety, 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;

   (e) emerging issues of significant health and safety relevance;

   (f) standardisation-related activities;

   (g) exchange of officials.

2. The Commission may provide third countries or international organisations with selected information from its Safety Gate system and receive relevant information on the safety of consumer products and on preventive, restrictive and corrective measures taken by those third countries or international organisations. The Commission shall share such information with national authorities, where relevant.

3. The information exchange referred to in paragraph 2 may take the form of either:

(a) a non-systematic exchange, in duly justified and specific cases;

(b) a systematic exchange, based on an administrative arrangement specifying the type of information to be exchanged and the modalities for the exchange.

4. Full participation in the Safety Gate system may be open to applicant countries and third countries, provided that their legislation is aligned with the relevant Union legislation and that they participate in the European Standardisation System. Such participation shall entail the same obligations as for Member States according to this Regulation, including notification and follow-up obligations. Full participation in the Safety Gate shall be based on agreements between the Union and those countries, according to arrangements defined in these agreements.

5. Any information exchange under this Article, to the extent it involves personal data, shall be carried out in accordance with Union data protection rules. Personal data shall only be transferred to the extent that such exchange is necessary for the sole purpose of the protection of consumers' health or safety.

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

CHAPTER X

Financial provisions

Article 37

Financing activities

1. The Union shall finance the following activities in relation to the application of this Regulation:

   (a) performance of the tasks of the Consumer Safety Network referred to in Article 28;

   (b) the development and operation of the Safety Gate referred to in Article 23, including the development of electronic interoperability solutions for:

   – the exchange of data between the Safety Gate and the national market surveillance systems;

   – the exchange of data between the Safety Gate and national customs systems;

   – the exchange of data with other relevant restricted systems used by market surveillance authorities for their enforcement purposes.

   (c) the development and maintenance of the Safety Gate portal referred to in Article 32 and the Safety Business Gateway, referred to in Article 25, including a public non-restricted software interface for data exchange with platforms and third parties.

2. The Union may finance the following activities in relation to the application of this Regulation:

   (a) the development of instruments of international cooperation referred to in Article 36;

   (b) the drawing up and updating of contributions to guidelines on market surveillance and product safety;

(c) the making available to the Commission of technical or scientific expertise for the purpose of assisting the Commission in its implementation of market surveillance administrative cooperation;

(d) the performance of preliminary or ancillary work in connection with the implementation of market surveillance activities linked to the application of this Regulation such as studies, programmes, evaluations, guidelines, comparative analyses, mutual joint visits and visit programmes, exchange of personnel, research work, the development and maintenance of databases, training activities, laboratory work, proficiency testing, inter-laboratory tests and conformity assessment work;

(e) Union market surveillance campaigns and associated activities, including resources and equipment, IT tools and training;

(f) activities carried out under programmes of technical assistance, cooperation with third countries and the promotion and enhancement of Union market surveillance policies and systems among interested parties at Union and international levels.

3. The Union's financial assistance to the activities under this Regulation shall be implemented in accordance with Regulation (EU, Euratom) No 2018/1046 of the European Parliament and of the Council[22], either directly, or indirectly by delegating budget implementation tasks to the entities listed in Article 62(1), point (c) of that Regulation.

4. The appropriations allocated to activities referred to in this Regulation shall be determined each year by the budgetary authority within the limits of the financial framework in force.

[22] 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 budgetary authority for the financing of market surveillance activities may also cover expenses pertaining to preparatory, monitoring, control, audit and evaluation activities which are required for the management of the activities pursuant to this Regulation and the achievement of their objectives; in particular, studies, meetings of experts, information and communication actions, including corporate communication of the political priorities of the Union as far as they are related to the general objectives of market surveillance activities, expenses linked to information technology networks focusing on information processing and exchange, together with all other technical and administrative assistance expenses incurred by the Commission for the management of the activities pursuant to this Regulation.

Article 38

Protection of the Union's financial interests

1. The Commission shall take appropriate measures to ensure that, when actions financed under this Regulation are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportionate and dissuasive administrative and financial penalties.

2. The Commission or its representatives and the Court of Auditors shall have the power of audit, on the basis of documents and of on-the-spot inspections, over all grant beneficiaries, contractors and subcontractors who have received Union funds under the Single Market Programme and its successor[23].

[23] OJ L292, 14.11.1996, p.2.

3. The European Anti-Fraud Office (OLAF) may carry out investigations, including on-the-spot checks and inspections, in accordance with the provisions and procedures laid down in Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council[24] and Council Regulation (Euratom, EC) No 2185/96[25], 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.

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

CHAPTER XI

Final provisions

Article 39

Liability

1. Any decision taken pursuant to this Regulation and involving restrictions on the placing of a product on the market or requiring its withdrawal or its recall shall not affect the assessment of the liability of the party concerned, in the light of the national law applying in the case in question.

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[24] 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).

[25] 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. This Regulation shall not affect Council Directive 85/374/EEC[26].

Article 40

Penalties

1. Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, by [insert date - 3 months after to the date of entry into force of this Regulation], notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.

2. Member States shall take into account at least the following indicative criteria for the imposition of penalties, where appropriate:

   (a) the duration or temporal effects of the infringement, the nature and the gravity, in particular the level of risk incurred by the consumer;

   (b) the number of dangerous products made available on the market or the number of consumers affected or both;

   (c) the role and responsibility of the economic operator or online marketplace;

   (d) any action taken by the economic operator or online marketplace to timely mitigate or remedy the damage suffered by consumers;

   (e) where appropriate, the intentional or negligent character of the infringement;

   (f) any previous infringements by the economic operator or online marketplace;

[26] 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).

(g) the financial benefits gained or losses avoided directly or indirectly by the economic operator or online marketplace due to the infringement, if the relevant data are available;

(h) the size of the undertaking;

(i) the degree of cooperation with the authority;

(j) the manner in which the infringement became known to the authority, in particular whether, and if so to what extent, the economic operator or online marketplace timely notified the infringement;

(k) any other aggravating or mitigating factor applicable to the circumstances of the case.

3. The types of infringements by economic operators or online marketplaces, where applicable, subject to penalties shall be any of the following:

(a) infringement of the general product safety requirement;

(b) failure to inform the authority in a timely manner about a dangerous product they placed on the market;

(c) failure to comply with any decision, order, interim measure, economic operator's commitment or other measure adopted pursuant to this Regulation;

(d) failure to comply with traceability and information obligations of economic operators referred to in Articles 8, 9, 10, 11 and 18 and 19;

(e) providing incorrect, incomplete or misleading information in response to a request from market surveillance authorities;

(f) failure to provide requested information within the required time-limit;

(g) refusal to submit to inspections;

(h) failure to provide the required documents or products during inspections;

(i) falsifying test results.

4. In the case of fines, the maximum amount of penalties shall be at least 4 % of the economic operator's or, where applicable, online marketplace's annual turnover in the Member State or Member States concerned.

5. Member States may also impose periodic penalty payments to compel economic operators or online marketplaces, where applicable:

(a) to put an end to a violation of the provisions of this Regulation;

(b) to comply with a decision ordering corrective measure;

(c) to supply complete and correct information;

(d) to submit to an inspection;

(e) to allow market surveillance authorities to perform data scraping of online interfaces.

6. By 31 March of each year, Member States shall inform the Commission of the type and the size of the penalties imposed under this Regulation, identify the actual infringements of this Regulation, and indicate the identity of economic operators or online marketplaces upon which penalties have been imposed.

7. Each year, the Commission shall elaborate and make public a report on the penalties imposed by Member States.

8. The information referred to in paragraph 6 shall not be published in the report referred to in paragraph 7 in any of the following circumstances:

(a) where it is necessary to preserve the confidentiality of an investigation or of national judicial proceedings;

(b) where publication would cause disproportionate damage to the economic operator or online marketplace;

(c) where a natural person is concerned, unless the publication of personal data is justified by exceptional circumstances, inter alia, by the seriousness of the infringement.

Article 41

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 17(3) shall be conferred on the Commission for an indeterminate period of time from [*insert date* - the date of entry into force of this Regulation].

3. The delegation of power referred to in Article 17(3) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following its publication in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016[27].

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

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

Article 42

Committee procedure

1. The Commission shall be assisted by a Committee. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

Article 43

Evaluation

1. By [insert date five years after the date of entry into force] the Commission shall carry out an evaluation of this Regulation. The Commission shall present a report on the main findings to the European Parliament, the Council and the European Economic and Social Committee. The report shall in particular assess if this Regulation achieved the objective of enhancing the protection of consumers against dangerous products while taking into account its impact on businesses and in particular on small and medium-sized enterprises.

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

Article 44

Amendments to Regulation (EU) No 1025/2012

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

In Article 10, the following paragraph 7 is added:

'7. Where a European standard drafted in support of Regulation (EU) …/… of the European Parliament and of the Council[28][*this Regulation (GPSR)*] satisfies the general safety requirement laid down in Article 5 of that Regulation and the specific safety requirements referred to in [Article [6] of that Regulation], the Commission shall publish a reference of such European standard without delay in the *Official Journal of the European Union*.'

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

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

‘1. When a Member State or the European Parliament considers that a harmonised standard or European standard drafted in support of Regulation (EU) …/… [*this Regulation (GPSR)*] does not entirely satisfy the requirements which it aims to cover and which are set out in the relevant Union harmonisation legislation or in that Regulation, it shall inform the Commission thereof with a detailed explanation. The Commission shall, after consulting the committee set up by the corresponding Union harmonisation legislation, if it exists, or the committee set up by Regulation (EU) …/… [*this Regulation (GPSR*)], or after other forms of consultation of sectoral experts, decide:

(a) to publish, not to publish or to publish with restriction the references to the harmonised standard or European standard drafted in support of Regulation (EU) …/… [*GPSR*] concerned in the *Official Journal of the European Union;*

(b) to maintain, to maintain with restriction or to withdraw the references to the harmonised standard or European standard drafted in support of Regulation (EU) …/… [*GPSR*] concerned in or from the *Official Journal of the European Union*.’

2. The Commission shall publish information on its website on the harmonised standards and European standards drafted in support of Regulation (EU) …/… [*GPSR*] that have been subject to the decision referred to in paragraph 1.

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

Article 45

Repeal

1. Directive 87/357/EEC and Directive 2001/95/EC are repealed with effect from [date of application].

2. References to Directives 87/357/EEC and 2001/95/EC shall be construed as references to this Regulation and to Regulation (EU) No 1025/2012, and shall be read in accordance with the correlation table in the Annex.

Article 46

Transitional provisions

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

Article 47

Entry into force and application

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

It shall apply from [6 *months after the entry into force of this Regulation*].

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

Done at Brussels,

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