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To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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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)

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## EXPLANATORY MEMORANDUM

### 1. CONTEXT OF THE PROPOSAL

- **Reasons for and objectives of the proposal**

This proposal for a Regulation on consumer product safety is in line with the New Consumer Agenda of 2020<sup>1</sup> aiming to: (i) update and modernise the general framework for the safety of non-food consumer products; (ii) preserve its role as a safety net for consumers; (iii) adapt the provisions to challenges posed by new technologies and online selling; and (iv) ensure a level playing field for businesses. While the proposal will replace the Directive 2001/95/EC on general product safety<sup>2</sup> ('GPSD'), it will continue applying to manufactured non-food consumer products. The proposed Regulation will also provide continuity with the GPSD by: (i) requiring that consumer products be 'safe'; (ii) setting certain obligations for economic operators; and (iii) containing provisions for the development of standards in support of the general safety requirement. It also aligns the market surveillance rules for products falling outside the scope of the EU harmonisation legislation ('non-harmonised products') with those applying to products falling under the scope of the EU harmonisation legislation ('harmonised products') as set out in Regulation (EU) 2019/1020. The proposed Regulation aims therefore both to update the rules currently set out in Directive 2001/95/EC to ensure a safety net for all products, and, at the same time, to ensure that the regime provides greater consistency between harmonised and non-harmonised products.

Already in 2011, the Single Market Act<sup>3</sup> identified the revision of the GPSD and of Regulation (EC) No 765/2008<sup>4</sup> as key actions 'to improve the safety of products circulating in the EU through better coherence and enforcement of product safety and market surveillance rules'. Such revision was proposed in 2013 in a package including the revision of both legal instruments, the purpose being to introduce a single legislative framework for harmonised and non-harmonised products. It was considered that overlaps in market surveillance rules and obligations of economic operators laid down in various pieces of EU legislation (GPSD, Regulation (EC) No 765/2008 and sector-specific EU harmonisation legislation) have led to confusion among economic operators and national authorities and have hampered the effectiveness of market surveillance activity in the EU. The proposed package stalled in negotiations for its adoption and was withdrawn. In the meantime, in 2017, following up on the 2015 Communication *Upgrading the Single Market: more opportunities for people and business*<sup>5</sup>, the Commission adopted a proposal to revise Regulation (EC) 765/2008 to strengthen product compliance and enforcement of EU harmonisation legislation on products,

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<sup>1</sup> Communication from the Commission to the European Parliament and the Council, New Consumer Agenda – *Strengthening consumer resilience for sustainable recovery*, COM(2020) 696 final.

<sup>2</sup> Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (Text with EEA relevance), OJ L 11, 15.1.2002, p. 4.

<sup>3</sup> Communication from the Commission to the European Parliament and the Council, the European Economic and Social Committee and the Committee of the Regions, Single Market Act – Twelve levers to boost growth and strengthen confidence – Working together to create new growth/\* COM/2011/0206 final.

<sup>4</sup> Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (Text with EEA relevance), OJ L 218, 13.8.2008, p. 30.

<sup>5</sup> Communication from the Commission to the European Parliament and the Council, the European Economic and Social Committee and the Committee of the Regions, *Upgrading the Single Market: more opportunities for people and business*, COM/2015/0550 final.

as part of the ‘goods package’, e.g. a package of initiatives to ensure a better functioning of the single market for goods. This led to the adoption, in 2019, of Regulation (EU) 2019/1020<sup>6</sup>.

- **Consistency with existing policy provisions in the policy area**

### **Regulation (EU) 2019/1020<sup>7</sup>**

Regulation (EU) 2019/1020 lays down rules and procedures for compliance with, and enforcement of, EU harmonisation legislation on products. The proposal seeks to enable better cooperation among national market surveillance authorities. To that end, it aims to clarify the procedures for the mutual assistance mechanism between them, and, for some product categories, it will require non-EU manufacturers to designate a natural or legal person responsible for compliance information. The proposal covers market surveillance of non-food products (‘industrial products’) whose placement on the single market is subject to EU harmonising acts. It is applicable, except for Chapter VII, to harmonised products only.

To ensure coherence and consistency between the regimes for harmonised and non-harmonised products, this proposal takes up and adapts a number of provisions of Regulation 2019/1020, such as Chapters IV, V and VI on market surveillance and Article 4.

### **Decision 768/2008/EC<sup>8</sup>**

Decision 768/2008/EC sets out common principles and procedures that EU legislation must follow when harmonising conditions for marketing products in the EU and the EEA. It includes reference requirements to be incorporated whenever product legislation is revised. As such, it is a template for future product harmonisation legislation.

To ensure consistency between the legislation for harmonised and non-harmonised products, this proposal takes up some of the provisions of Decision 768/2008/EC, such as those on traceability requirements and the obligations of economic operators.

### **Regulation (EU) 1025/2012<sup>9</sup>**

Regulation (EU) 1025/2012 provides a legal basis to use European standards for products and services, identify ICT technical specifications, and finance the European standardisation process. It also sets an obligation for European standardisation organisations (CEN, CENELEC, ETSI) and national standardisation bodies on transparency and participation.

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<sup>6</sup> Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011, OJ L 169, 25.6.2019, p. 1.

<sup>7</sup> Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011, OJ L 169, 25.6.2019, p. 1.

<sup>8</sup> Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (Text with EEA relevance), OJ L 218, 13.8.2008, p. 82.

<sup>9</sup> Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council, L 316, 14.11.2012, p. 12.

To ensure consistency with the general regime for standardisation as provided for by Regulation (EU) 1025/2012, this proposal provides for a number of amendments to Regulation (EU) 1025/2012 to adapt it to the specific characteristics of the proposed regulation, in particular to the fact that this Regulation requires the adoption of specific safety requirements and to the fact that the standards adopted under this regulation cannot be assimilated to harmonised standards and are indicated therefore as “European standards”.

### **Directive (EU) 2019/771<sup>10</sup>**

Directive 2019/771 introduces rules on the conformity of goods, remedies in the event of a lack of conformity and how to make use of those remedies.

The proposal provides remedies specifically for dangerous products that have been recalled from the market. This particular situation justifies having a set of rules that are partially different and easier to activate, in particular because the consumer does not need to demonstrate the non-conformity of the product. These rules are applicable only if products are recalled. Therefore they do not amend Directive 2019/771 but only add additional protection in the case of recall.

### **Regulation (EU) 2019/881<sup>11</sup>**

The Cybersecurity Act introduces an EU-wide cybersecurity certification framework for ICT products, services and processes. However, it does not include minimum cybersecurity legal requirements for ICT products. This proposal clarifies that cybersecurity risks that have an impact on the safety of consumers are covered by the concept of safety under the proposed Regulation.

- **Consistency with other EU policies**

The following ongoing or planned initiatives at EU level play an important role for product safety:

The **Digital Services Act (DSA)**, adopted by the Commission on 15 December 2020<sup>12</sup>, aims to regulate the responsibilities of providers of intermediary services online, including online platforms such as social media and online marketplaces, with regard to illegal content, goods or services offered by their users. That proposal sets out a number of due diligence obligations for online platforms relevant for the proposed regulation, including the introduction of the ‘traceability of traders’ principle and the obligation to take into consideration product safety law in structuring the interface (Article 22). The DSA covers all types of illegal content, as defined by national or EU law, including the sale of dangerous products online. As the DSA is a legislative instrument of general application, it does not include specific provisions addressing such type of content. The DSA also sets out the framework for the notice and

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<sup>10</sup> Directive (EU) 2019/771 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the sale of goods, amending Regulation (EU) 2017/2394 and Directive 2009/22/EC, and repealing Directive 1999/44/EC (Text with EEA relevance), OJ L 136, 22.5.2019, p. 28.

<sup>11</sup> Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act), OJ L 151, 7.6.2019, p. 15.

<sup>12</sup> Proposal for a regulation of the European Parliament and of the Council on a Single Market For Digital Services (Digital Services Act) and amending Directive 2000/31/EC, COM/2020/825 final.

action procedure (Article 14). The proposed regulation specifies certain obligations for online marketplaces in the product safety field.

The **legislative proposal on artificial intelligence (AI)** lays down harmonised rules for the placing on the market, putting into service and use of artificial intelligence systems in the EU. The rules need to ensure a high level of protection of the public interests, in particular on health and safety, and people's fundamental rights and freedoms. It lays down specific requirements with which high-risk AI systems must comply and imposes obligations on providers and users of such systems.

This proposal takes into consideration these provisions and provides a safety net for products and risks to health and safety of consumers that do not enter into the scope of application of the AI proposal.

The **chemicals strategy** adopted in October 2020<sup>13</sup> points to the fact that the already widespread use of chemicals will increase, including in consumer products, and that it is necessary to ban the most harmful chemicals in consumer products to ensure their safety. The **REACH Regulation**<sup>14</sup> has introduced obligations for the industry to assess and manage the risks posed by chemicals and provide appropriate safety information for their users. It also provides for restrictions to protect human health and the environment from unacceptable risks posed by chemicals. This proposal maintains a safety net for chemical risks in products not covered by specific legislation.

The **Circular economy action plan** adopted in March 2020<sup>15</sup> aims to reduce waste through reuse, repair, remanufacturing and high-quality recycling - in particular concerning secondary raw materials where dangerous substances can persist - and states that the safety of products must be taken into consideration as a primary objective. This proposal acknowledges that, when economic operators or authorities face a choice of corrective actions, the most sustainable action (i.e. the one with the lowest environmental impact) should be preferred, provided that it does not result in a lower level of safety.”

## 2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

### • Legal basis

The legal basis for the proposed Regulation is Article 114 TFEU, with due regard to Article 169<sup>16</sup>. Its objective is to ensure product safety and improve the functioning of the internal market. At the same time, it aims to ensure a high level of consumer protection, by

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<sup>13</sup> Communication from the Commission to the European Parliament and the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability – Towards a Toxic-Free Environment, COM/2020/667 final.

<sup>14</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, p.1.

<sup>15</sup> Communication from the Commission to the European Parliament and the Council, the European Economic and Social Committee and the Committee of the Regions A new Circular Economy Action Plan For a cleaner and more competitive Europe COM/2020/98 final.

<sup>16</sup> Article 169 makes reference to Article 114 to achieve its objectives.



contributing to protect the health and safety of European consumers and promoting their right to information<sup>17</sup>.

- **Subsidiarity (for non-exclusive competence)**

The proposal harmonises the general product safety requirement in the EU. Ensuring the safety of products in the single market cannot be achieved sufficiently by Member States acting alone for the following reasons:

- Products circulate freely across the single market. When a dangerous product is identified in a certain country it is very likely that the same product could be found in other Member States too, not least because of the exponential growth of online selling.
- Different rules on product safety at national level can create uneven costs for businesses to comply with product safety legislation, and therefore can cause distortions in the level playing field on the internal market.
- To ensure a high level of consumer protection, the EU must contribute to protecting the health and safety of consumers. If different countries have different rules, consumers will not be protected against dangerous products in the same way across the EU.
- To be effective, market surveillance must be uniform across the EU. If market surveillance is ‘softer’ in some parts of the EU, weak spots are created. These threaten the public interest, create unfair trading conditions and encourage ‘forum shopping’<sup>18</sup>.

EU-level action on product safety for non-harmonised products has the following added value:

- Common rules and standards for product safety at EU level mean that businesses no longer have to comply with heterogeneous sets of national rules. This generates benefits in terms of costs savings, a lower administrative burden and a less complex legal regime for businesses. This also enables free circulation of goods in the EU and allows for closer cooperation between Member States.
- Common EU rules allow economies of scale in market surveillance, particularly important with the exponential development of online selling, which intensifies cross-border sales and direct imports from outside the EU. The costs of market surveillance are also shared through joint market surveillance actions and the exchange of information among EU countries.
- The functioning of the single market will be improved by EU-level action. Common product safety and market surveillance rules across the EU will ensure a more even treatment of businesses, and therefore will be less likely to distort the level playing field on the EU single market.
- EU action allows for faster and more efficient circulation of information, in particular via the Safety Gate/RAPEX system, thus ensuring fast action against dangerous products across the EU and a level playing field.

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<sup>17</sup> Also, product safety is part of the high level of consumer protection ensured by EU policies (see Article 38 of the Charter of Fundamental Rights of the European Union) and is therefore one of the pillars of EU consumer protection policy.

<sup>18</sup> Traders trying different entry points to the EU.

- At international level, the common set of provisions established under the GPSD has also enabled the EU to be stronger in promoting a high level of safety both bilaterally and multilaterally, thus tackling the increasing circulation of goods from third countries via online selling.

- **Proportionality**

This proposal strikes a careful balance between, on the one hand, EU countries' regulatory autonomy in setting the level of consumer protection and market surveillance they consider necessary, and, on the other hand, the need to address product safety issues that have to be tackled centrally. As underlined in Chapter 7 of the impact assessment, the challenges remain considerable, with a high presence of unsafe consumer products on the EU market. The costs and regulatory burdens associated with this proposal have been kept as limited as possible. Total costs for businesses in the EU27 in the first year of implementation of this Regulation is estimated at 0.02% of turnover of EU companies for manufacturing, wholesale and retail of non-harmonised products. The measures included in this proposal do not extend beyond what is necessary to solve the identified problems and to achieve the objectives set. The foreseen costs for the Commission and Member States are considered as acceptable, and will be compensated by the savings incurred by businesses, and benefits for businesses, consumers and Member States alike.

- **Choice of the instrument**

A regulation is the only suitable instrument to achieve the objective of improving enforcement of, and compliance with EU legislation on product safety ensuring coherence in the implementation of its legal framework. A directive would not sufficiently achieve the objectives, as jurisdictional boundaries and potential jurisdictional conflicts would persist following its transposition. 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 harmonised products, where the applicable legal instrument is also a Regulation (Regulation (EU) 2019/1020). Finally, such a choice will further reduce the regulatory burden through a consistent application of product safety rules across the EU.

### 3. **RESULTS OF *EX POST* EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS**

- ***Ex post* evaluations/fitness checks of existing legislation**

This proposal for a regulation builds on the evaluation of the General Product Safety Directive, conducted as a 'back-to-back' evaluation with the impact assessment accompanying the proposal. The GPSD has a twofold objective. It pursues the aim of **improving the functioning of the single market**, by introducing a common legislative framework to avoid disparities between Member States that could have emerged in the absence of EU law. At the same time, the GPSD intends to achieve a **high level of consumer protection** by introducing a general product safety requirement and other measures. Both aims are interrelated: the harmonised safety requirement for consumer products envisaged by the GPSD prevents disparities that would lead to the creation of barriers to trade and distortion of the level playing field within the single market.

The evaluation concluded that the role of the GPSD as a cornerstone of consumer safety and the functioning of the single market is uncontested. Its objectives remain fully relevant, and its EU added value cannot be denied. The GPSD's role as a 'safety net' remains essential for consumer protection, as it provides a legal basis aimed to ensure that no dangerous products end up in consumers' hands. The establishment of the rapid alert system for dangerous non-

food products under the GPSD has proven to be a success. However, the evaluation has exposed a number of factors that question how far some provisions of the GPSD still contribute to the proper achievement of its goals.

In the first place, the growth of **e-commerce** has decreased the effectiveness of the GPSD. The GPSD applies to all consumer products, regardless of whether they are sold in bricks-and-mortar shops or online. However, the lack of explicit provisions in the GPSD to address the specificities of online selling, in particular the appearance of new actors in the online supply chain, has negatively affected the safety of EU consumers and the level playing field for compliant EU businesses.

The rapid development of **new technologies** also raises questions about the scope of some of the key concepts of the GPSD. The appearance of some new risks linked to connectivity, the applicability of the Directive to software updates and downloads as well as the evolving functionalities of AI-powered products raise the question whether the GPSD is clear enough to provide legal certainty for businesses and protection to consumers.

The evaluation has also identified a lack of internal coherence in the EU legal framework, with the existence of two different sets of rules on **market surveillance** for harmonised and non-harmonised products.

Finally, it is apparent from the evaluation that it would be necessary to fine-tune some of the provisions to improve the effectiveness of the GPSD. In particular, legislative changes or further actions are needed to improve the effectiveness of **product recalls**. There is also a need for a mechanism to arbitrate disputes between Member States regarding risk assessments. The **traceability system** under the Directive and the **resources constraints of market surveillance authorities** make it difficult to effectively control the safety of products, and consequently need to be tackled to ensure the proper protection of consumers and functioning of the Single market. Also, the **Food-Imitating Products Directive (FIPD)** is currently not enforced in a harmonised manner among Member States, so a solution to address this issue is needed.

- **Stakeholder consultations**

In preparing this proposal, the Commission consulted stakeholders via a public consultation on the inception impact assessment and roadmap, an open public consultation (OPC), stakeholder workshops, as well as ad hoc contributions and targeted consultations with Member States and other stakeholders. The results from the consultation activities have been incorporated throughout the impact assessment and are reflected in this proposal. The main points raised during the consultations are the following:

**Preserving the safety net:** The overall feedback among all stakeholder groups was that the GPSD is a useful piece of legislation and its safety net principle should be preserved. However, a large majority of respondents stated that current EU safety rules for non-food consumer products covered by the GPSD could be improved in specific areas so that they better protect consumers (71% of answers in the OPC).

**Tackling the challenges posed by new technologies:** While all stakeholders acknowledged that new technologies raise many challenges, they put forward divergent approaches to tackle them. In the consultations, consumer representatives and several Member State authorities expressed support for expanding the definition of ‘safety’ to include (cyber)security aspects that have an impact on safety. However, in the consultation on the roadmap/inception impact assessment, technology-oriented businesses were more reluctant to include new technologies and new risks related to them in the GPSD. They would prefer the GPSD to remain technology-neutral, with risks linked to new technologies covered in other, more specific

pieces of legislation. Nevertheless, the proposal for a regulation includes such aspects to make sure that risks posed by new technologies are in the scope of the safety net, in case they are not covered by more specific pieces of EU legislation<sup>19</sup>.

**Addressing safety issues associated with products sold online:** The issue of products coming directly or via online platforms from outside the EU was a recurrent issue mentioned in the consultations. Businesses and business representatives stressed the importance of having a level playing field and pointed out that currently many EU retailers suffer as a result of unfair competition from operators based in third countries. Member State authorities stressed that it was difficult to control products coming from third countries and to take enforcement action against economic operators outside the EU. Views diverged between stakeholders regarding the obligations of online marketplaces:

- Online marketplaces providing their feedback on the roadmap indicated that they would accept some of the obligations under the current voluntary Product Safety Pledge being binding, but would not be in favour of further obligations.<sup>20</sup> Retailers argued that online marketplaces play a key role in the supply chain, and therefore they should have corresponding responsibilities.
- Consumer representatives and Member States authorities were in favour of strengthening responsibilities across the supply chain.

**Improving market surveillance rules and enforcement:** As regards market surveillance and enforcement, stakeholders from all categories were in favour of an alignment of market surveillance rules between harmonised and non-harmonised products. This is included in the proposal. Regarding the introduction of a ‘responsible person’ in the revised GPSD, a large majority of respondents in the OPC considered that products covered by the GPSD should only be placed on the EU market if there is an economic operator established in the EU responsible for product safety purposes (70% of respondents in favour).

**Revision of the standardisation process:** A majority of stakeholders was in favour of simplifying the standardisation process for developing new standards under the GPSD and now under this Regulation. This is provided for in this proposal.

**Including food-imitating products in the scope of the revised GPSD:** Most stakeholders were in favour of incorporating the food-imitating legislation into the revised GPSD. A large majority of respondents to the OPC stated that products which resemble foodstuff should be incorporated into the general product safety legal instrument (69% of respondents in favour). In the consultation on the inception impact assessment, respondents favoured including this element in the product safety risk assessment. This approach is reflected in the proposal. No support was expressed for a full ban of food-imitating products.

**Improving the framework for product recalls:** Stakeholders repeatedly stressed the crucial importance of contacting affected consumers directly in the case of recalls whenever possible, for instance because the product was registered, bought online, or bought with the use of loyalty card. Several stakeholders mentioned that consumers should be able to choose to receive safety notifications only (when registering a product or subscribing to a loyalty scheme). There was a broad agreement that some key elements and ground rules, applicable to all recall notices, should be standardised and made compulsory, which is the case in the

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<sup>19</sup> Please see the opinion of the Sub-group on Artificial Intelligence (AI), connected products and other new challenges in product safety to the Consumer Safety Network of December 2020.

<sup>20</sup> Feedbacks received on the roadmap: [General Product Safety Directive – review \(europa.eu\)](https://ec.europa.eu/europa/en/press-room/press-releases/2020-12-23-general-product-safety-directive-review)

proposed regulation. Several stakeholders mentioned the need to make recall participation less burdensome and more attractive to consumers.

**Improving traceability along the supply chain:** A large majority of stakeholders agreed that the system of product traceability should be strengthened in the GPSD (82% in favour in the OPC). Moreover, the role of online marketplaces in improving product traceability was also stressed, with respondents notably arguing that marketplaces should check that traceability information is available before listing a product.

**Addressing counterfeit products:** Brand owner organisations stressed that the GPSD should be amended to tackle counterfeit unsafe products. This issue was duly taken into consideration but not included in this proposal, as counterfeit products are already addressed by EU legislation, and unsafe products are covered in the GPSD and in this proposal regardless of their authenticity. Even though counterfeit products can pose safety risks, the safety of a given product has to be analysed based on a risk assessment.

- **Collection and use of expertise**

The preparatory steps for this proposal rest on expert advice and a number of studies. This includes studies with a focus on the GPSD's implementation, to support the evaluation and impact assessment, as well as on the effectiveness of product recalls.

The Commission also gathered expertise and views through targeted consultations and engagement activities, including a series of workshops, conferences, interviews with experts and authorities, and the opinion of the Sub-group of the Consumer Safety Network on artificial intelligence, connected products and other new challenges on product safety. The Commission held numerous bilateral meetings and carried out an analysis of ad-hoc position papers from consumer organisations, industry representatives and academia.

- **Impact assessment**

This proposal is supported by an impact assessment report (SWD (2021) 169, SWD (2021) 168). The impact assessment report has been scrutinised by the Regulatory Scrutiny Board and received a positive opinion (SEC 280 (avis du RSB))

In the context of this initiative, the Commission examined several policy alternatives as presented in the impact assessment report. The range of policy alternatives analysed included both non-legislative and legislative actions to address the different specific objectives as presented in the report: (i) ensure the EU legal framework provides general safety rules for all consumer products and risks, including products and risks linked to new technologies; (ii) address product safety challenges in the online sales channels; (iii) make product recalls more effective and efficient to keep unsafe products away from consumers; (iv) enhance market surveillance and ensure better alignment of rules for harmonised and non-harmonised consumer products; and finally (v) address safety issues related to food-imitating products.

A number of options were assessed. First, the Commission considered how it could respond to the specific objectives without revising the GPSD (Option 1). Several non-legislative measures have been considered, in particular: (i) issuing guidance documents on the applicability of the GPSD to new technologies and on recalls and; (ii) exploring expansion of the voluntary measures under the Product Safety Pledge for online sales. However, the different consultations showed that such non-legally binding measures would not tackle the identified shortcomings.

The Commission considered several legislative options to tackle the specific objectives: a targeted legislative revision of the GPSD (Option 2) focusing on a limited number of changes and a full revision of the GPSD proposing a comprehensive action on all objectives (Option 3). The impact assessment shows that Option 3, which is more ambitious than Option 2, also better addresses the identified shortcomings and better meets the specific objectives to be addressed, while keeping the economic impacts still limited. Option 4 considered a full integration of market surveillance instruments, as proposed in the 2013 product safety and market surveillance package, to analyse whether this option would still be valid after the recent adoption of Regulation (EU) 2019/1020. The impact assessment showed that Option 4, although similar on substance to Option 3, might generate higher costs for EU businesses. Therefore, the Commission chose Option 3 (full revision of the GPSD including change to a regulation) as the best policy choice for the current proposal since it addresses best the policy objectives while limiting the costs for businesses and market surveillance authorities.

Different options have also been considered regarding the safety of food-imitating products. These were: (i) to maintain a separate regime for these products under a separate directive (revising Directive 87/357/EEC); (ii) to integrate the specific provisions of the current Directive 87/357/EEC into the new GPSD with a specific legal regime; (iii) to abandon targeted provisions on food-imitating products and use the general provisions to ensure safety of such products based on the case-by-case risk assessment instead. For the first two options, the Commission also considered developing guidance to overcome the issue of different interpretation by Member States; however, consulting the Member States showed that the divergences in interpretation of the Food-Imitating Products Directive were so great that a legal revision of the rules was necessary to ensure its even application. The Commission chose as the best policy option discontinuing the specific regime for food-imitating products and assessing their safety according to the same risk assessment principles as for the other non-harmonised consumer products (the food-imitating aspect will be taken into account in the risk assessment of the given product).

The preferred option, which includes: a) clarification on how this legislation would apply to risks posed by new technologies and online selling, b) provisions enhancing the effectiveness of product recalls, c) alignment with harmonised market surveillance rules and ensuring better responsibilities related to products safety of economic operators and online marketplaces, d) simplification of standardisation procedures and e) integration of the provisions of the Food Imitating Products Directive, is expected to have the following impacts:

On economic impacts, the preferred option is expected to lead to major benefits for consumers and society. The estimated consumer detriment should decrease by approximately EUR 1.0 billion in the first year of implementation of the preferred option and by approximately EUR 5.5 billion over the next decade. This option should also reduce consumer detriment related to ineffective recalls by more than EUR 400 million per year. Moreover, by reducing the number of unsafe products, the proposed measures should also reduce the current detriment suffered by EU consumers and society due to preventable product-related accidents (estimated today at EUR 11.5 billion per year) and the current cost of healthcare for product-related injuries (current estimate EUR 6.7 billion per year). The precise impact could not be quantified due to lack of injury data to estimate trends. Estimated cost savings caused by reducing the differences in national implementation and legal fragmentation are estimated at EUR 59 million annually for businesses and EUR 0.7 million per year for market surveillance authorities.

Total costs for businesses in the EU (active in manufacturing, wholesale and retail of non-harmonised products) are estimated at EUR 196.6 million, equivalent to 0.02% of their

turnover in the first year of implementation. In the following years, the recurrent costs would amount to EUR 177.8 million for EU businesses. These costs are linked to the increased obligations for businesses mainly for online sales, sales of new technology products and recalls of unsafe products, and to the alignment of market surveillance rules with those for harmonised products. Market surveillance authorities in Member States would face total additional recurrent costs under this proposal of approximately EUR 6.7 million annually due to their increased powers in the market surveillance of unsafe products, and only relatively moderate one-off adaptation and implementation costs.

- **Regulatory fitness and simplification**

This proposal envisages revising two existing legislative instruments: the General Product Safety Directive and the Food-Imitating Product Directive. To simplify the legislation, the Commission proposes to repeal the Food-Imitating Product Directive and assess the safety of food-imitating products under the current proposal for a new general product safety regulation.

The Commission also identified several areas where the administrative burden and related costs could be reduced.

First, this proposal would reduce regulatory costs and burdens for businesses, since the legally binding clarifications and the choice of a regulation as instrument will reduce regulatory uncertainty and ensure more even implementation of the product safety legislation compared to today under the GPSD. Also, aligning the general market surveillance and safety requirements for harmonised and non-harmonised products will reduce implementation differences and improve the traceability of the supply chain. Cost reductions will occur for all businesses, and in particular for the 42% of businesses who reported additional costs related to the uneven implementation of the GPSD. Cost savings for businesses through more harmonised implementation are estimated at around EUR 59 million annually (EUR 34 million saved by EU SMEs and EUR 26 million saved by EU large businesses respectively).

Second, this proposal will bring efficiency gains in market surveillance and enforcement to Member States. This is due to aligning market surveillance provisions between harmonised and non-harmonised products, more aligned enforcement powers, increased deterrent effect and a new arbitration mechanism. Therefore, this proposal brings cost reductions for all market surveillance authorities in Member States, and in particular for the 16% of them who reported related additional costs due to the different legal frameworks between harmonised and non-harmonised products. These cost savings for Member States are estimated at EUR 0.7 million per year across the EU.

Finally, the proposed simplification of the standardisation process will reduce the administrative burden for Member States and the Commission. Such streamlining of the standardisation EU process will accelerate standardisation work and thus increase legal certainty and help companies to comply with the general product safety requirement.

This proposal does not exempt micro-enterprises and SMEs from any of the obligations. EU product safety legislation does not allow for 'lighter' regimes for SMEs since any consumer product must be safe whatever the characteristics of its supply chain in order to meet the general objective of product safety and consumer protection. The Commission estimates the total compliance costs of this proposal for EU SMEs at EUR 111.1 million (one-off and recurrent costs) in the first year of implementation. In the subsequent years, the recurrent costs would amount to around EUR 100 million for EU SMEs. Estimated savings caused by reduced differences in national implementation and legal fragmentation would amount to EUR 34 million for EU SMEs.

This proposal will have practical implications both on the economic operators handling products covered by the GPSD and on market surveillance authorities in the Member States.

Businesses will have to comply with additional requirements regarding traceability and transparency. Additional requirements on recalls will apply for businesses that have actually brought unsafe products onto the market. Online marketplaces will also have to make sure they set up internal mechanisms to comply with their new obligations relating to product safety. In addition, companies selling in the single market from outside the EU will have to set up arrangements to ensure that the products sold in the EU have a responsible economic operator.

Member States' market surveillance authorities might require additional resources to cope with the broadening of market surveillance responsibilities and the new competences they would be given. For example, the new tools for market surveillance online broaden the possibilities for national authorities and may require additional resources and skills. However, with these new powers being largely aligned with the existing market surveillance provisions applicable to harmonised products under Regulation (EU) 2019/1020, market surveillance authorities are often familiar with them, in particular in those Member States where the same national market surveillance authorities handle already both harmonised and non-harmonised products. The practical implications for Member States are therefore rather better synergies and better use of existing structures and resources than new additional needs. The extended coverage of risks from new technologies (e.g. cybersecurity risks that have an impact on safety) would be expected to increase the need for professional staff and external expertise in Member States to check the safety of new technology products.

The most affected business sectors would be online sales and producers in some new technology sectors. However, thanks to harmonised EU requirements this should not have a major impact on their competitiveness.

This proposal operates effectively in both the digital and physical worlds and takes into account digital developments, in particular the development of online sales and new technology products. Addressing the digital challenges for product safety is one of the main objectives of this proposal. It improves market surveillance rules for online sales and sets product safety obligations for online marketplaces and online retailers to improve the safety of products sold online. This proposal also addresses new safety risks brought by new technologies and clarifies the application of product safety rules to software. This proposal is fully consistent with the EU's digital policies in place and in particular with the proposal for the Digital Services Act and with the legislative work on artificial intelligence and the internet of things. This initiative is supported by existing ICT solutions, namely the EU Rapid Alert System for dangerous non-food products ('Safety Gate') and the related Business Gateway.

- **Fundamental rights**

This proposal aims to strengthen the protection of European consumers' health and safety and promote their right to information. Thanks to clearer obligations and better product safety enforcement, this proposal is expected to have a positive impact on, and ensure a higher level of, consumer protection and environmental protection, in line with Articles 37 and 38 of the Charter of Fundamental Rights of the European Union.

The proposal imposes additional requirements on businesses that are necessary to pursue the general EU interest of increasing consumer protection. The resulting compliance costs are estimated to be comparatively low compared to businesses' turnover. As such, these requirements do not affect the fundamental freedom to conduct a business and its proportionality under Article 52 of the Charter.



#### **4. BUDGETARY IMPLICATIONS**

The proposed regulation requires the Commission to support and facilitate the cooperation of market surveillance enforcement authorities, including coordinated market surveillance activities, the new arbitration mechanism and peer reviews. Furthermore, this proposal allows for enhanced cooperation and exchange of information with EU international partners in the product safety field. Finally, this proposal provides for the adoption of implementing acts and delegated acts (related to traceability and recalls) and possible higher standardisation activity through a simplified standardisation procedure. This will trigger additional workload for the Commission, estimated at four extra full-time officials (three administrators and one assistant). These resources will be obtained through the redistribution and refocusing of the existing personnel's tasks.

The Commission will also finance electronic interfaces, namely the Safety Gate webpage, the Safety Gate portal (which provides notifications of dangerous products) and the Safety Business Gateway collecting notifications from economic operators to market surveillance authorities.

Additional costs for these coordination activities and electronic interfaces can be covered by the single market programme under the current multiannual financial framework 2021-2027. Similar financing possibilities may also be included under the successor programmes under future multiannual financial frameworks. The details are set out in the financial statement attached to this proposal.

#### **5. OTHER ELEMENTS**

- **Implementation plans and monitoring, evaluation and reporting arrangements**

The implementation of the proposal will be accompanied by monitoring based on predefined core enforcement indicators. The Commission is carrying out a study to define a common set of feasible and relevant enforcement indicators in the product safety field, to be agreed with Member States.

In addition to the regular monitoring and reporting, an evaluation of the effectiveness, efficiency, relevance, coherence and EU added value of this legislative intervention is proposed after 5 years of implementation by Member States.

The Commission will support the implementation of the proposal by coordination actions, both in the context of the Consumer Safety Network (follow-up of implementation, exchange of best practices between Member States, etc.) and the market surveillance coordinated activities (CASPs).

- **Detailed explanation of the specific provisions of the proposal**

The proposed regulation consists of 11 chapters comprising 47 articles.

##### **Chapter I – General provisions**

This chapter sets out the scope and the main terms used in the proposed regulation. It provides a 'safety net' for all products falling under its scope of application establishing requirements to ensure the safety of consumer products and therefore the safety of consumers. It provides rules on the application of this Regulation to the non-harmonised legislation. It updates the definitions used in Directive 2001/95/EC, in particular to take into account the different scope of the definition of product, and introduces a specific definition of 'online marketplace'

##### **Chapter II – Safety requirements**

It introduces the general safety requirement, confirms the importance of standards published in the EU Official Journal as providing presumption of safety and updates aspects for assessing the safety of products to take into consideration food-imitating products in the risk evaluation, following the repeal of Directive 87/357/EEC. New aspects for assessing product safety also include the possible risks related to products based on new technologies.

### **Chapter III – Obligations of economic operators**

#### **Section 1**

This Section set outs the obligations of the economic operators except those economic operators which fall under the scope of application of Regulation (EU) 2019/1020. This is to avoid that obligations contained in this Chapter could conflict with similar obligations contained in the harmonised legislation. Apart of the more general obligations of economic operators to ensure the safety of products, it introduces the concept of substantial modification, in which case responsibility for the safety of the product shifts to the person making the modification. Furthermore, it extends the concept of person responsible contained in Article 4 of Regulation (EU) 2019/1020 to non-harmonised products. This is a necessary condition for making the products available on the market to tackle the issues of direct imports from third countries. This chapter also contains the basic provisions on traceability, mostly taken from Decision 768/2008/EC, and the possibility, in the case of products susceptible to pose a serious risk to people's health and safety, to adopt a more stringent system of traceability, to be adopted by a delegated act.

#### **Section 2**

This Section contains the obligations of economic operators which are applicable also to economic operators falling under the scope of Regulation (EU) 2019/1020. These are obligations which do not have correspondence in the harmonised sectors and therefore their applicability also to this sector would not create conflict. It concerned the obligation of economic operators in case of distance sales and in case of accidents with a product.

### **Chapter IV – Online marketplaces**

This Chapter examines the role played by online marketplaces and lays down specific obligations applicable to them.

### **Chapter V– Market surveillance and implementation**

This chapter takes up and adapts the entire Chapters IV, V and VI of Regulation (EU) 2019/1020 on market surveillance. The aim is to create, as far as possible, a single regime for both harmonised and non-harmonised products.

### **Chapter VI – Safety Gate rapid alert system**

This chapter lays down the principle for exchanging information in the case of a dangerous product and changes the name of the RAPEX system to Safety Gate, while maintaining the same characteristics of the system. The proposal adds more specific deadlines. The relation between Safety Gate and the Information and Communication System on Market Surveillance (ICSMS) is made clearer; the chapter also clarifies that Member State authorities can decide to entrust the task of single liaison officer to the Safety Gate National contact point.

### **Chapter VII – Commission role and enforcement coordination**

This chapter provides the possibility for the Commission to adopt measures, through implementing acts, in case of a serious risk which cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned or by any other procedure under EU legislation. This possibility already exists in the GPSD: the proposed regulation makes its

scope of application more precise. Chapter V also introduces a voluntary arbitration mechanism where Member States can submit to the Commission questions concerning the identification or the level of a risk linked to a product in case of diverging risk assessments. This will make it possible to take more uniform action at EU level against dangerous products.

### **Chapter VIII – Right to information and remedy**

This chapter provides provisions on information for consumers. It confirms the obligation for the Commission and Member States to make available to consumers information relating to risks to health and safety posed by products. It also sets the obligation for Member States to give consumers the opportunity to submit complaints to the competent national authorities. It confirms and further enhances the scope of the Safety Gate web portal, which already exists, adding a new section where consumers can consult warnings and recalls issued directly by economic operators. On recalls, the new provisions try to improve their effectiveness, thus ensuring a more complete and widespread provision of information for consumers, as well as an enhanced system of remedies available to consumers.

### **Chapter IX– International cooperation**

This Chapter provides the legal basis for the Commission to establish forms of cooperation to improve product safety. These include common enforcement actions, technical support, exchange of officials, and the exchange of information on dangerous products and in particular information contained in the Safety Gate. In this respect, the provision allows either fully fledged participation in Safety Gate or an exchange of selected information.

### **Chapter X – Financial provisions**

The proposed Regulation provides for the financing by the Commission of activities in all matters falling under its scope of application.

The proposed Regulation includes general clauses on protecting the financial interests of the EU.

### **Chapter XI - Final provisions**

This chapter provides in particular for a system of penalties: while recognising that establishing penalties is a national competence, it sets out guiding principle for penalties, in particular criteria for setting penalties, the types of infringements to be penalised, criteria on maximum ceilings, as well as the possibility to impose periodic penalty payments.

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<sup>21</sup>,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Directive 2001/95/EC of the European Parliament and of the Council<sup>22</sup> lays down the requirement that consumer products must be safe and that Member States' market surveillance authorities must take action against dangerous products as well as exchange information to that effect through the “Union rapid information exchange system”, RAPEX.
- (2) Directive 2001/95/EC needs to be revised and updated in light of the developments related to new technologies and online selling, to ensure consistency with developments in the Union harmonisation legislation and in the standardisation legislation, to ensure a better functioning of the product recalls as well as to ensure a clearer framework for food-imitating products so far regulated by Council Directive 87/357/EEC<sup>23</sup>. In the interest of clarity, Directive 2001/95/EC, as well as Directive 87/357/EEC, should be repealed and replaced by this Regulation.
- (3) A Regulation is the appropriate legal instrument as it imposes clear and detailed rules which do not give room for divergent transposition by Member States. The choice of

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<sup>21</sup> .OJ C , , p. .

<sup>22</sup> Directive 2001/95/EC of the European Parliament and of the Council on general product safety (OJ L 11, 15.1.2002, p. 4).

<sup>23</sup> Council Directive 87/357/EEC of 25 June on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers (OJ L 192, 11.7. 1987, p. 49).

Regulation instead of Directive also allows to better deliver on the objective to ensure coherence with the market surveillance legislative framework for products falling under the scope of Union harmonisation legislation as set out in Regulation (EU) 2019/1020, where the applicable legal instrument is also of the same type, namely Regulation (EU) 2019/1020 of the European Parliament and of the Council<sup>24</sup>. Finally, such a choice will further reduce the regulatory burden through a consistent application of product safety rules across the Union.

- (4) The aim of this 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)

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<sup>24</sup> Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1).

2019/1020 of the European Parliament and of the Council<sup>25</sup>, therefore the provisions regulating the Safety Gate and its functioning contained in this Regulation should be applicable to Union harmonisation legislation.

- (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) 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.
- (11) Considering also the broad scope given to the concept of health<sup>26</sup>, 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<sup>27</sup> or by other food specific legislation which only covers chemical and biological food-related risks.

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<sup>25</sup> Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1).

<sup>26</sup> 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.

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

- (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<sup>28</sup> are subject to the regulatory control of the Member States, in light of their limited risk to civil aviation safety. They should therefore be excluded from the scope of this Regulation.
- (16) The requirements laid down in this Regulation should apply to second hand products or products that are repaired, refurbished 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.
- (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 which is operated 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.
- (19) Items which connect to other items or non-embedded items which influence the way another item works can present a risk for the safety of the product. That aspect should be taken into due consideration as a potential risk. The connections and interrelation that an item might have with external items should not jeopardise its safety.
- (20) New technologies 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,

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<sup>28</sup> Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1–122).

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.
- (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<sup>29</sup> provides the general framework for e-commerce and lays down certain obligations for online platforms. Regulation [.../...] on a Single Market for Digital Services (Digital Services Act) and amending Directive 2000/31/EC<sup>30</sup> 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

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<sup>29</sup> Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') - OJ L 178, 17.7.2000, p. 1–16.

<sup>30</sup> Regulation [.../...] on a Single Market for Digital Services (Digital Services Act) and amending Directive 2000/31/EC.



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.
- (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<sup>31</sup>, 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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<sup>31</sup> Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council (OJ L 304, 22.11.2011, p. 64).

- (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.
- (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<sup>32</sup> 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.
- (66) Where the Commission identifies a need for a European standard ensuring compliance of certain products with the general safety requirement under this Regulation, it should apply the relevant provisions of Regulation (EU) No 1025/2012 of the European Parliament and of the Council<sup>33</sup> to request one or several European standardisation organisations to either draft or identify a standard which is suitable to ensure that products which conform to it are presumed to be safe.
- (67) Certain provisions of Regulation (EU) 1025/2012 should be amended to take the specificities of this Regulation into account, and in particular the need to define the specific safety requirements under this Regulation before launching the request to the European standardisation organisation.
- (68) Together with the adaptation of Regulation (EU) 1025/2012, a specific procedure for the adoption of the specific safety requirements with the assistance of the specialised Committee provided for by this Regulation should be introduced.
- (69) 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.
- (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

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<sup>32</sup> Directive (EU) 2019/771 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the sale of goods, amending Regulation (EU) 2017/2394 and Directive 2009/22/EC, and repealing Directive 1999/44/EC (OJ L 136, 22. 5. 2019, p. 28).

<sup>33</sup> Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14. 11. 2012, p. 12).

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<sup>34</sup> and Regulation (EU) 2018/1725 of the European Parliament and of the Council<sup>35</sup>. 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.
- (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

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<sup>34</sup> 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).

<sup>35</sup> 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).



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<sup>36</sup>.

- (77) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the health and safety of consumers, imperative grounds of urgency so require.
- (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<sup>37</sup>. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.
- (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.

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<sup>36</sup> Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

<sup>37</sup> OJ L 123, 12.5.2016, p. 1.

(81) The European Data Protection Supervisor was consulted in accordance with Article 42 of Regulation (EU) 2018/1725 and delivered an opinion on XX XXXX.<sup>38</sup>

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 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 which is operated 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;

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<sup>38</sup> ...

- (i) antiques.
3. This Regulation shall apply to products placed or made available on the market whether new, used, repaired or reconditioned. It shall not apply to products to be repaired or reconditioned prior to being used where those products are made available on the market 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 item, interconnected or not to other items, supplied or made available, 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;

10. ‘importer’ means any natural or legal person established within the Union who places a product from a third country on the Union market;
11. ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;
12. ‘fulfilment service provider’ means any natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved, excluding postal services as defined in Article 2, point 1 of Directive 97/67/EC of the European Parliament and of the Council<sup>39</sup>, parcel delivery services as defined in Article 2, point 2 of Regulation (EU) 2018/644 of the European Parliament and of the Council<sup>40</sup>, and any other postal services or freight transport services;
13. ‘economic operator’ means the manufacturer, the authorized representative, the importer, the distributor, the fulfilment service provider or any other natural or legal person who is subject to obligations in relation to the manufacture of products, making them available on the market in accordance with this Regulation;
14. ‘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;
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;

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<sup>39</sup> Directive 97/67/EC of the European Parliament and of the Council of 15 December 1997 on common rules for the development of the internal market of Community postal services and the improvement of quality of service (OJ L 15, 21. 1. 1998, p. 14).

<sup>40</sup> Regulation (EU) 2018/644 of the European Parliament and of the Council of 18 April 2018 on cross-border parcel delivery services (OJ L 112, 2. 5. 2018, p. 19).

22. ‘market surveillance authority’ means an authority designated by a Member State under Article 10 of Regulation (EU) 2019/1020 as responsible for organising and carrying out market surveillance in the territory of that Member State;
23. ‘recall’ means any measure aimed at achieving the return of a product that has already been made available to the consumer;
24. ‘withdrawal’ means any measure aimed at preventing a product in the supply chain from being made available on the market;
25. ‘Union harmonisation legislation’ means Union legislation listed in Annex I to Regulation (EU) 2019/1020 and any other Union legislation harmonising the conditions for the marketing of products to which that Regulation applies.

#### *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*

##### **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 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 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 safe use and disposal, and any other indication or information regarding the product;
  - (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;
  - (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 third 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, 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;
  - (f) national standards drawn up in the Member State in which the product is made available;
  - (g) the state of the art and technology, including the opinion of recognized scientific bodies and expert committees;
  - (h) product safety codes of good practice in force in the sector concerned;
  - (i) reasonable consumer expectations concerning safety;
  - (j) safety requirements adopted in accordance with Article 6(2).

## **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 conformity 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<sup>41</sup> or, if that methodology is not appropriate for the product concerned, it shall give a detailed description of the methodology used;
  - (b) specifying the type of data, which economic operators shall collect and store by means of the traceability system referred to in paragraph 2;
  - (c) 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.

## 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

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<sup>41</sup> Commission Implementing Decision (EU) 2019/417 of 8 November 2018 laying down guidelines for the management of the European Union Rapid Information System 'RAPEX' established under Article 12 of Directive 2001/95/EC on general product safety and its notification system (OJ L 73, 15.3.2019, p. 121).

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. 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’ 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 ‘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’ in Articles 10 to 16, Articles 18 and 19 and Articles 21 to 24 of Regulation (EU) 2019/1020 shall be read as reference to ‘failure to comply with this Regulation’;
  - (e) the reference to ‘Article 41’ in Article 14(4), point (i) of Regulation (EU) 2019/1020 shall be read as reference to ‘Article 40 of this Regulation’;
  - (f) the reference to ‘Article 20’ in Article 19(1) of Regulation (EU) 2019/1020 shall be read as reference to ‘Article 24 of this Regulation’.
3. Where a dangerous product has been identified, the manufacturer shall indicate, upon request by market surveillance authorities, which other products, produced with the same procedure, containing the same components or being part of the same production batch, 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, data concerning the implementation of this Regulation.
2. The Commission, by means of implementing acts, shall determine the output indicators on the basis of which Member States have to communicate this data. Those implementing acts shall be adopted in accordance with the 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.
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<sup>42</sup>, either directly, or indirectly by delegating

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<sup>42</sup> Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

budget implementation tasks to the entities listed in Article 62(1), point (c) of that Regulation.

4. The appropriations allocated to activities referred to in this Regulation shall be determined each year by the budgetary authority within the limits of the financial framework in force.
5. The appropriations determined by the budgetary authority for the financing of market surveillance activities may also cover expenses pertaining to preparatory, monitoring, control, audit and evaluation activities which are required for the management of the activities pursuant to this Regulation and the achievement of their objectives; in particular, studies, meetings of experts, information and communication actions, including corporate communication of the political priorities of the Union as far as they are related to the general objectives of market surveillance activities, expenses linked to information technology networks focusing on information processing and exchange, together with all other technical and administrative assistance expenses incurred by the Commission for the management of the activities pursuant to this Regulation.

### *Article 38*

#### **Protection of the Union's financial interests**

1. The Commission shall take appropriate measures to ensure that, when actions financed under this Regulation are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportionate and dissuasive administrative and financial penalties.
2. The Commission or its representatives and the Court of Auditors shall have the power of audit, on the basis of documents and of on-the-spot inspections, over all grant beneficiaries, contractors and subcontractors who have received Union funds under the Single Market Programme and its successor<sup>43</sup>.
3. The European Anti-Fraud Office (OLAF) may carry out investigations, including on-the-spot checks and inspections, in accordance with the provisions and procedures laid down in Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council<sup>44</sup> and Council Regulation (Euratom, EC) No 2185/96<sup>45</sup>, with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with a grant agreement or grant decision or a contract funded under the programme.
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

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<sup>43</sup> OJ L292, 14.11.1996, p.2.

<sup>44</sup> Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1).

<sup>45</sup> Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

provisions expressly empowering the Commission, the Court of Auditors and OLAF to conduct such audits and investigations, in accordance with their respective competences.

## CHAPTER XI

### Final provisions

#### *Article 39*

##### **Liability**

1. Any decision taken pursuant to this Regulation and involving restrictions on the placing of a product on the market or requiring its withdrawal or its recall shall not affect the assessment of the liability of the party concerned, in the light of the national law applying in the case in question.
2. This Regulation shall not affect Council Directive 85/374/EEC<sup>46</sup>.

#### *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;
  - (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;

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<sup>46</sup> Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 210, 7.8.1985, p. 29).

- (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<sup>47</sup>.
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.

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<sup>47</sup> OJ L 123, 12.5.2016, p. 1

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<sup>48</sup>[*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*.’

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*;

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<sup>48</sup> 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 ...)’

- (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*  
*The President*

*For the Council*  
*The President*

## LEGISLATIVE FINANCIAL STATEMENT

### **1. FRAMEWORK OF THE PROPOSAL/INITIATIVE**

#### **1.1. Title of the proposal/initiative**

#### **1.2. Policy area(s) concerned**

#### **1.3. The proposal/initiative relates to:**

#### **1.4. Objective(s)**

*1.4.1. General objective(s)*

*1.4.2. Specific objective(s)*

*1.4.3. Expected result(s) and impact*

*1.4.4. Indicators of performance*

#### **1.5. Grounds for the proposal/initiative**

*1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative*

*1.5.2. Added value of Union involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this point 'added value of Union involvement' is the value resulting from Union intervention which is additional to the value that would have been otherwise created by Member States alone.*

*1.5.3. Lessons learned from similar experiences in the past*

*1.5.4. Compatibility with the Multiannual Financial Framework and possible synergies with other appropriate instruments*

*1.5.5. Assessment of the different available financing options, including scope for redeployment*

#### **1.6. Duration and financial impact of the proposal/initiative**

#### **1.7. Management mode(s) planned**

### **2. MANAGEMENT MEASURES**

#### **2.1. Monitoring and reporting rules**

#### **2.2. Management and control system(s)**

*2.2.1. Justification of the management mode(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed*

*2.2.2. Information concerning the risks identified and the internal control system(s) set up to mitigate them*

*2.2.3. Estimation and justification of the cost-effectiveness of the controls (ratio of "control costs ÷ value of the related funds managed"), and assessment of the expected levels of risk of error (at payment & at closure)*

#### **2.3. Measures to prevent fraud and irregularities**

### **3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE**



**3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected**

**3.2. Estimated financial impact of the proposal on appropriations**

*3.2.1. Summary of estimated impact on operational appropriations*

*3.2.2. Estimated output funded with operational appropriations*

*3.2.3. Summary of estimated impact on administrative appropriations*

*3.2.4. Compatibility with the current multiannual financial framework*

*3.2.5. Third-party contributions*

**3.3. Estimated impact on revenue**

## 1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

### 1.1. Title of the proposal/initiative

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on general product safety and repealing Council Directive 87/357/EEC and Directive 2001/95/EC

### 1.2. Policy area(s) concerned

Title: 03 – Single Market –

Chapter: 03 02 Single Market Programme

Item: 03 02 04 Empowering consumer and civil society and ensuring high level of consumer protection and product safety including the participation of end users in financial services policy-making

### 1.3. The proposal/initiative relates to:

a new action

a new action following a pilot project/preparatory action<sup>49</sup>

the extension of an existing action

a merger or redirection of one or more actions towards another/a new action

### 1.4. Objective(s)

#### 1.4.1. General objective(s)

Consumer protection, fairer and deeper internal market; digital single market.

To ensure that only safe products are placed on the internal market and to assure a high level of consumer safety and protection and a level-playing field for businesses in the Single Market.

The aim of the proposal is to revise Directive 2001/95/EC on general product safety to ensure that EU consumers are protected from dangerous products, while ensuring proper functioning of the Single market, in particular level playing field for businesses.

The purpose of proposed budgeted action is to continue and further develop the cooperation measures related to market surveillance (including at international level), the financing of the electronic interfaces allowing exchange of data and informing the consumers and economic operators on dangerous products and to implement the new proposal (via implementing and delegated acts and increased standardisation activities).

#### 1.4.2. Specific objective(s)

Specific objective No

1. Reinforcing market surveillance cooperation procedures among enforcement authorities, reducing fragmentation and inefficiencies;

<sup>49</sup> As referred to in Article 58(2)(a) or (b) of the Financial Regulation.

2. Increasing operational capacity, improving efficiency and availability of resources for coordination of enforcement and implementation of the proposal (monitoring, delegated acts), increasing the use of standardisation procedure;
3. Strengthening the enforcement toolbox, allowing market surveillance authorities to use more deterrent, effective and future-proof tools;
4. Improving the exchange of information on dangerous products both inside the EU and with external partners (including via IT tools). Improving information to businesses and consumers on dangerous products via IT tools;
5. Promoting compliance with EU product safety legislation on non-harmonised consumer products.

The objectives cover market surveillance within the EU and at the external borders and encompass digital as well as traditional supply chains.

#### 1.4.3. *Expected result(s) and impact*

*Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.*

The target population will be all European Union consumers who will benefit from safe products placed on the internal market. Increased market surveillance will benefit European producers by preventing unfair level playing field with businesses that do not respect their obligations to protect consumer health and safety.

#### 1.4.4. *Indicators of performance*

*Specify the indicators for monitoring progress and achievements.*

The monitoring of the implementation of the proposal will be based on predefined core monitoring and enforcement indicators. The Commission will start monitoring the implementation of the revised GPSD after the entry into force of the initiative.

The Impact Assessment identified a set of monitoring indicators proposed to monitor the achievement of the policy objectives identified (see section 9 of the Impact Assessment).

The monitoring will be done mainly by the Commission, based on regular EU-wide consumer surveys, data provided by businesses and MSAs and data from the Safety Gate. The monitoring and evaluation will be done on the basis of existing data sources where possible.

The proposal sets out reporting obligations for Member States. This reporting will be done on the basis of enforcement indicators which will be further defined by a study. The Commission is carrying out a study aiming to define a common set of feasible and relevant enforcement indicators in the product safety field, to be agreed with Member States.

The Commission has also mapped existing sources of injury information and looked into the possibility of establishing an EU-level injury database to help the implementation of the product safety legislation. It is currently assessing the costs and benefits of setting up such an EU wide injury database (via coordinated actions with Member States).

In addition to the regular monitoring and reporting, an evaluation of the effectiveness, efficiency, relevance, coherence and EU added value of this legislative intervention is proposed 5 years after implementation by Member States of this proposal.

## 1.5. Grounds for the proposal/initiative

### 1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative

This proposal aims to meet the following achievements:

The assessment of risk presented by new technology products will improve as of the adoption of the proposal allowing thereby a better safety net function of the legislative act.

In the short term, we expect improvement of the safety of consumer products bought online thanks to better market surveillance rules for online sales and increased obligations on product safety for online marketplaces.

The market surveillance rules for non-harmonised products will be aligned with those of harmonised products. Furthermore, some improvements of the market surveillance rules under this initiative for market surveillance of all products will enhance market surveillance and ensure higher product safety in the medium term.

The proposed improvement of the current Safety Gate/RAPEX system will make the exchange of information more rapid, allowing earlier corrective actions.

Effectiveness of product recalls is expected to increase in the short term thanks to the enhanced recall procedure and better information to consumers.

Increased efficiency at Commission level in the standardisation process for non-harmonised products will facilitate setting standards for these products: we can expect to have an increased number of standards in the medium term. The increased use of European standards will give producers greater certainty that their products comply with the relevant safety requirements and will permit businesses to compete on a level-playing field by ensuring that they have equal opportunities.

The proposal will harmonise the risk assessment of food-imitating products and thereby ensure their equal treatment across the Member States.

### 1.5.2. Added value of Union involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this point 'added value of Union involvement' is the value resulting from Union intervention which is additional to the value that would have been otherwise created by Member States alone.

Reasons for action at European level (ex-ante)

EU involvement in product safety for non-harmonised products has clear benefits demonstrated by the evaluation of the GPSD and the impact assessment of this proposal:

- Common Union rules allow economy of scale in market surveillance, in particular due to the exponential development of online selling which intensifies cross-border sales and direct imports from outside the EU. Sharing costs of market surveillance occurs also by performing joint market surveillance actions among EU countries and exchange information.
- EU action allows faster and more efficient circulation of information, in particular via the Safety Gate/RAPEX, thus ensuring fast actions against dangerous products across the EU and level playing field.

- Common rules for product safety at EU level have benefits in term of costs savings and lower administrative burden and complexities for businesses by avoiding them having to comply with heterogeneous sets of national rules. This enables also free circulation of goods in the EU and allows for closer cooperation between Member States.
- Common Union rules enable developing EU product safety standards, which by giving EU-wide presumption of safety facilitate product safety compliance for businesses (and potentially decrease the related costs).
- At international level, the common set of provisions established by the GPSD has also allowed the EU to be stronger in promoting a high level of safety with international actors, thus tackling the increasingly high circulation of goods from third countries via online selling.

Expected generated Union added value (ex-post)

The functioning of the internal market will be improved by EU level action since coherent product safety and market surveillance rules across the EU will ensure a more even treatment of businesses and therefore less likely distorted competition on the EU Single Market. Better market surveillance and enhanced coordination between Member States will lead to higher detection of unsafe products, and thus to higher consumer protection and trust.

### 1.5.3. *Lessons learned from similar experiences in the past*

The Union adopted its first general product safety regulation in 1992. The current GPSD was adopted in 2001. The Evaluation of the current GPSD and the stakeholder views showed that the GPSD is still a very valid instrument in particular thanks to its “safety net” function. It appears overall to have met its objectives of ensuring a high level of safety of consumers, while ensuring an effectively operating internal market for goods; however, we observe that still too many unsafe products reach or remain in the hands of consumers, which provides the grounds for the current proposal.

### 1.5.4. *Compatibility with the Multiannual Financial Framework and possible synergies with other appropriate instruments*

The aim of the proposal is to revise Directive 2001/95/EC on general product safety to ensure that EU consumers are protected from dangerous products, while ensuring proper functioning of the Single Market, in particular level-playing field for businesses. Therefore, it fits perfectly into Art.3(2)(d) of the Single Market Programme Regulation that is to empower consumer and civil society and ensure a high level of consumer protection and product safety.

The financial impact on operational appropriations will be entirely covered by the allocations foreseen in the MFF 2021-27 under the financial envelopes of the Single Market Programme.

The proposal is one of the legal initiatives under the New Consumer Agenda.

The proposal ensures a better alignment with the provisions of Regulation (EU) 2019/1020 on market surveillance and compliance of products. The proposal, as a safety net, is compatible and complementary to harmonised legislation in two ways. First, it applies in its entirety to consumer products falling outside the scope of harmonised legislation (e.g. furniture, childcare articles, clothes). Secondly, it applies partially to consumer products covered by harmonised legislation (e.g. toys or cars)

as long as aspects of product safety covered by the GPSD are not covered in the harmonised legislation.

The safety of food products is regulated separately under the General Food Law Regulation (EC) No 178/2002. However, the Regulation (EC) No 1935/2004 on food contact materials can interact with the proposal when it comes to products containing such materials (e.g. reusable lunch boxes) and remains compatible. Unsafe products containing food-contact materials products might be subject to safety alerts in both alert systems, RASFF for food and Safety Gate/RAPEX for non-food products.

The proposal is fully consistent and compatible with the other EU policies and recent proposals to strengthen enforcement in other policy areas, such as:

- Digital Services Act (DSA): The DSA proposal aims to establish new obligations for online intermediaries inter alia in relation with how they handle all types of illegal content hosted on their websites including unsafe products. The DSA establishes the general horizontal obligations for online intermediaries and leaves room for legislation in relation with specific types of illegal content (such as product safety) to be more specific. This proposal will also regulate other product safety aspects of online sales beyond the role of online intermediaries, such as the role of sellers and the powers of market surveillance authorities.

- Artificial Intelligence (AI) horizontal framework: it aims to focus on high-risk applications. Consequently, and with respect to product safety, it will function like sectorial legislation, establishing specific requirements for AI applications, and this proposal will apply as a safety net for products and aspects not covered by other sectorial legislation to provide a legal basis for withdrawing such products to ensure an effective protection of consumers.

- NIS Directive: The recent proposal lays down obligations for all Member States to adopt a national strategy on the security of network and information systems to enhance cybersecurity across the EU. However, it does not include minimum cybersecurity requirements for consumer products, so it does not provide any legal basis for authorities to take action against products presenting such risks.

- Circular Economy: According to the new Circular Economy Action Plan, products placed on the EU market should be more sustainable and therefore designed to last longer, to be easier to repair and upgrade, recycle and reuse. It is essential that repaired, upgraded, recycled or reused products continue to meet product safety requirements. According to the eco-design directive, safety and health have to be taken into account in the choice of a specific design solution; however safety issues related to the end products are not specifically addressed. The Sustainable Product Policy Initiative (which will replace the eco-design directive and extend its scope) will notably aim at correcting the fact that many products cannot be easily and safely reused, repaired or recycled. In case some safety aspects related to products in the circular economy are not specifically addressed by initiatives from the Circular Economy Action Plan, the safety net function of this proposal comes into play.

There is thus no overlap, but complementarity between these initiatives. The advantage of integrating aspects of substantive alternative policy areas into product safety legislation is therefore to ensure a real safety net for consumers, making possible that that all non-food consumer products on the EU market are safe.

1.5.5. *Assessment of the different available financing options, including scope for redeployment*

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## 1.6. Duration and financial impact of the proposal/initiative

### limited duration

- in effect from [DD/MM]YYYY to [DD/MM]YYYY
- Financial impact from YYYY to YYYY for commitment appropriations and from YYYY to YYYY for payment appropriations.

### unlimited duration

- Implementation with a start-up period from YYYY to YYYY,
- followed by full-scale operation.

## 1.7. Management mode(s) planned<sup>50</sup>

### Direct management by the Commission

- by its departments, including by its staff in the Union delegations;
- by the executive agencies

### Shared management with the Member States

### Indirect management by entrusting budget implementation tasks to:

- third countries or the bodies they have designated;
  - international organisations and their agencies (to be specified);
  - the EIB and the European Investment Fund;
  - bodies referred to in Articles 70 and 71 of the Financial Regulation;
  - public law bodies;
  - bodies governed by private law with a public service mission to the extent that they provide adequate financial guarantees;
  - bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that provide adequate financial guarantees;
  - persons entrusted with the implementation of specific actions in the CFSP pursuant to Title V of the TEU, and identified in the relevant basic act.
- *If more than one management mode is indicated, please provide details in the 'Comments' section.*

### Comments

The executive agency could manage the contractual aspects of specific projects under the supervision of the parental DG.

<sup>50</sup> Details of management modes and references to the Financial Regulation may be found on the BudgWeb site:  
<https://myintracomm.ec.europa.eu/budgweb/EN/man/budgmanag/Pages/budgmanag.aspx>



## 2. MANAGEMENT MEASURES

### 2.1. Monitoring and reporting rules

*Specify frequency and conditions.*

The proposal includes an evaluation obligation.

The IT system called “Safety Gate” that connects market surveillance authorities and the Commission will be strengthened by this proposal. By using the IT system the monitoring of operational activity could take place on an ongoing basis in an efficient manner.

The monitoring through the IT system will be completed by the work of the existing Consumer Safety Network and the provision by Member States of more reliable and more comprehensive information on product safety and enforcement activity of non-harmonised products as part of their national enforcement strategies.

Achievement of the specific objectives will be monitored on the basis of the pre-defined indicators.

### 2.2. Management and control system(s)

#### 2.2.1. *Justification of the management mode(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed*

Direct management by the Commission will allow to maintain direct contacts with the Member States authorities and the stakeholders engaged in the activities. Through direct management, the Commission can better adapt the actions to the needs of the policy to have more flexibility to re-adjust priorities in case of emerging needs and contribute to the common objectives of the Union.

#### 2.2.2. *Information concerning the risks identified and the internal control system(s) set up to mitigate them*

Operational risks concern the Safety Gate IT system: risk that the IT-system fail to effectively support the cooperation of market surveillance authorities and the Consumer Safety Network.

Operational risks also concern the level of resources dedicated to the market surveillance authorities at the level of Member States.

To mitigate them, effective IT-governance processes, which actively involve the systems’ users, are implemented.

#### 2.2.3. *Estimation and justification of the cost-effectiveness of the controls (ratio of "control costs ÷ value of the related funds managed"), and assessment of the expected levels of risk of error (at payment & at closure)*

The costs of controls are negligible compared to the appropriations for the development of the IT system itself.

### 2.3. Measures to prevent fraud and irregularities

*Specify existing or envisaged prevention and protection measures, e.g. from the Anti-Fraud Strategy.*

The measures implemented by the Commission will be subject to the ex-ante and ex-post controls in accordance with the Financial Regulation. Contracts and agreements financing the implementation of this Regulation will expressly entitle the

Commission, including OLAF and the Court of Auditors to conduct audits, on-the-spot checks and inspections.

### 3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

#### 3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing budget lines

*In order of multiannual financial framework headings and budget lines.*

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff. <sup>51</sup>	from EFTA countries <sup>52</sup>	from candidate countries <sup>53</sup>	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation
1	03.020401	Diff.	YES	NO	NO	NO

<sup>51</sup> Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.

<sup>52</sup> EFTA: European Free Trade Association.

<sup>53</sup> Candidate countries and, where applicable, potential candidates from the Western Balkans.

### 3.2. Estimated financial impact of the proposal on appropriations

#### 3.2.1. Summary of estimated impact on operational appropriations

- The proposal/initiative does not require the use of operational appropriations
- The proposal/initiative requires the use of operational appropriations, as explained below:

EUR million (to three decimal places)

Heading of multiannual financial framework		Number 1								
DG: JUST			Year 2024 <sup>54</sup>	Year 2025	Year 2026	Year 2027	Enter as many years as necessary to show the duration of the impact (see point 1.6)			TOTAL
• Operational appropriations							<b>Post 2027</b>			
Budget line <sup>55</sup> 03.020401	Commitments	(1a)	7,000	7,000	7,000	7,000				<b>28,000</b>
	Payments	(2a)	2,100	7,000	7,000	7,000	4,900			<b>28,000</b>
Appropriations of an administrative nature financed from the envelope of specific programmes <sup>56</sup>										
Budget line 03010101		(3)	0,200	0,200	0,200	0,200				<b>0,800</b>
<b>TOTAL appropriations for DG JUST</b>	Commitments	=1a+1b+3	7,200	7,200	7,200	7,200				<b>28,800</b>
	Payments	=2a+2b+3	<b>2,300</b>	<b>7,200</b>	<b>7,200</b>	<b>7,200</b>	<b>4,900</b>			<b>28,800</b>

<sup>54</sup> Year N is the year in which implementation of the proposal/initiative starts. Please replace "N" by the expected first year of implementation (for instance: 2021). The same for the following years.

<sup>55</sup> According to the official budget nomenclature.

<sup>56</sup> Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

<b>Heading of multiannual financial framework</b>	<b>7</b>	‘Administrative expenditure’
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This section should be filled in using the 'budget data of an administrative nature' to be firstly introduced in the Annex to the Legislative Financial Statement (Annex V to the internal rules), which is uploaded to DECIDE for interservice consultation purposes.

EUR million (to three decimal places)

		Year 2024	Year 2025	Year 2026	Year 2027	Enter as many years as necessary to show the duration of the impact (see point 1.6)			TOTAL
<b>DG: JUST</b>									
• Human resources		3,054	3,054	3,054	3,054				12,216
• Other administrative expenditure		0,095	0,095	0,095	0,095				0,380
<b>TOTAL DG JUST</b>	Appropriations	<b>3,149</b>	<b>3,149</b>	<b>3,149</b>	<b>3,149</b>				<b>12,596</b>

<b>TOTAL appropriations under HEADING 7 of the multiannual financial framework</b>	(Total commitments = Total payments)	<b>3,149</b>	<b>3,149</b>	<b>3,149</b>	<b>3,149</b>				<b>12,596</b>
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EUR million (to three decimal places)

		Year 2024 <sup>57</sup>	Year 2025	Year 2026	Year 2027	Enter as many years as necessary to show the duration of the impact (see point 1.6)			TOTAL
<b>TOTAL appropriations under HEADINGS 1 to 7 of the multiannual financial framework</b>	Commitments	10,349	10,349	10,349	10,349				<b>41,396</b>
	Payments	5,449	10,349	10,349	10,349	4,900			<b>41,396</b>

<sup>57</sup> Year N is the year in which implementation of the proposal/initiative starts. Please replace "N" by the expected first year of implementation (for instance: 2021). The same for the following years.

3.2.2. Estimated output funded with operational appropriations

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs ↓			Year 2024	Year 2025	Year 2026	Year 2027	Enter as many years as necessary to show the duration of the impact (see point 1.6)										TOTAL		
	OUTPUTS																		
	Type <sup>58</sup>	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	Total No	Total cost	
SPECIFIC OBJECTIVE No 1 <sup>59</sup>			Reinforcing market surveillance cooperation procedures among enforcement authorities, reducing fragmentation and inefficiencies																
Coordinated activities for the safety of product	activities	0,300	10	3,000	10	3,000	10	3,000	10	3,000							40	12,000	
Studies, peer reviews, piloting national products safety strategies	reports	0,200	2	0,400	2	0,400	2	0,400	2	0,400							8	1,600	
Subtotal for specific objective No 1			<b>12</b>	<b>3,400</b>	<b>12</b>	<b>3,400</b>	<b>12</b>	<b>3,400</b>	<b>12</b>	<b>3,400</b>							<b>48</b>	<b>13,600</b>	
SPECIFIC OBJECTIVE No 2 ...			Increasing operational capacity, improving efficiency and availability of resources for coordination of enforcement and implementation of the proposal (monitoring, delegated acts), increasing the use of standardisation procedure																
Implementation of the proposal (delegated acts, monitoring, standardisation)																			

<sup>58</sup> Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

<sup>59</sup> As described in point 1.4.2. ‘Specific objective(s)...’

Subtotal for specific objective No 2																			
SPECIFIC OBJECTIVE No 3			Strengthening the enforcement toolbox, allowing market surveillance authorities to use more deterrent, effective and future-proof tools																
Big data and other innovative tools in online	data collec. IT tools	0,125	2	0,250	2	0,250	2	0,250	2	0,250									1,000
Subtotal for specific objective No 3			<b>2</b>	<b>0,250</b>	<b>2</b>	<b>0,250</b>	<b>2</b>	<b>0,250</b>	<b>2</b>	<b>0,250</b>									<b>1,000</b>
SPECIFIC OBJECTIVE No 4			Improving the exchange of information on dangerous products both inside the EU and with external partners (including via IT tools). Improving information to businesses and consumers on dangerous products via IT tools																
Safety Gate galaxy	IT systems	0,166	9	1,500	9	1,500	9	1,500	9	1,500									6,000
Exchange of data with international partners and other international cooperation	Linkage with other systems	0,35	3	1,050	3	1,050	3	1,050	3	1,050									4,200
Subtotal for specific objective No 4			<b>12</b>	<b>2,550</b>	<b>12</b>	<b>2,550</b>	<b>12</b>	<b>2,550</b>	<b>12</b>	<b>2,550</b>									<b>10,200</b>
SPECIFIC OBJECTIVE No 5			Promoting compliance with EU product safety legislation on non-harmonised consumer products.																
Promotion and communication activities	Conferences, press, campaign	0,2	4	0,800	4	0,800	4	0,800	4	0,800									3,200
Subtotal for specific objective No 5			<b>4</b>	<b>0,800</b>	<b>4</b>	<b>0,800</b>	<b>4</b>	<b>0,800</b>	<b>4</b>	<b>0,800</b>									<b>3,200</b>
<b>TOTALS</b>				<b>7,000</b>		<b>7,000</b>		<b>7,000</b>		<b>7,000</b>									<b>28,000</b>

### 3.2.3. Summary of estimated impact on administrative appropriations

- The proposal/initiative does not require the use of appropriations of an administrative nature
- The proposal/initiative requires the use of appropriations of an administrative nature, as explained below:

EUR million (to three decimal places)

	Year 2024 <sup>60</sup>	Year 2025	Year 2026	Year 2027	Enter as many years as necessary to show the duration of the impact (see point 1.6)			TOTAL
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HEADING 7 of the multiannual financial framework								
Human resources	3,054	3,054	3,054	3,054				<b>12,216</b>
Other administrative expenditure	0,095	0,095	0,095	0,095				<b>0,380</b>
<b>Subtotal HEADING 7 of the multiannual financial framework</b>	<b>3,149</b>	<b>3,149</b>	<b>3,149</b>	<b>3,149</b>				<b>12,596</b>
<b>TOTAL</b>	<b>3,149</b>	<b>3,149</b>	<b>3,149</b>	<b>3,149</b>				<b>12,596</b>

The appropriations required for human resources and other expenditure of an administrative nature will be met by appropriations from the DG that are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

<sup>60</sup> Year N is the year in which implementation of the proposal/initiative starts. Please replace "N" by the expected first year of implementation (for instance: 2021). The same for the following years.



### 3.2.3.1. Estimated requirements of human resources

- The proposal/initiative does not require the use of human resources.
- The proposal/initiative requires the use of human resources, as explained below:

*Estimate to be expressed in full time equivalent units*

	Year 2024	Year 2025	Year 2026	Year 2027	Enter as many years as necessary to show the duration of the impact (see point 1.6)		
<b>• Establishment plan posts (officials and temporary staff)</b>							
20 01 02 01 (Headquarters and Commission's Representation Offices)	18	18	18	18			
20 01 02 03 (Delegations)							
01 01 01 01 (Indirect research)							
01 01 01 11 (Direct research)							
Other budget lines (specify)							
<b>• External staff (in Full Time Equivalent unit: FTE)<sup>61</sup></b>							
20 02 01 (AC, END, INT from the 'global envelope')	5	5	5	5			
20 02 03 (AC, AL, END, INT and JPD in the delegations)							
<b>XX 01 xx yy zz</b> <sup>62</sup>	- at Headquarters						
	- in Delegations						
01 01 01 02 (AC, END, INT - Indirect research)							
01 01 01 12 (AC, END, INT - Direct research)							
Other budget lines (specify)							
<b>TOTAL</b>	<b>23</b>	<b>23</b>	<b>23</b>	<b>23</b>			

XX is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Description of tasks to be carried out:

Officials and temporary staff	<p>Preparation of delegated acts (related to traceability and recalls), set-up the new cooperation activities (new arbitration mechanism, peer reviews, cooperation with the Union Product Compliance Network), pilot national product safety enforcement strategies, improving interlinks with other databases (ICSMS, customs), international cooperation and monitoring of the Regulation. Preparation of implementing acts for the standardisation activities.</p> <p>AD staff for product safety and market surveillance, technical and legal analysis, joint actions management, specific market surveillance expertise, project management, Safety Gate coordination and implementation, international cooperation, the Secretariat of the Consumer Safety Network, communication and promotion activities, IT and data-systems supervision and financial management tasks.</p> <p>AST staff for support to meeting organisation and all administrative tasks.</p>
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<sup>61</sup> AC= Contract Staff; AL = Local Staff; END= Seconded National Expert; INT = agency staff; JPD= Junior Professionals in Delegations.

<sup>62</sup> Sub-ceiling for external staff covered by operational appropriations (former 'BA' lines).

External staff	Routine IT maintenance and specific development projects –.
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### 3.2.4. *Compatibility with the current multiannual financial framework*

The proposal/initiative:

- can be fully financed through redeployment within the relevant heading of the Multiannual Financial Framework (MFF).

Explain what reprogramming is required, specifying the budget lines concerned and the corresponding amounts. Please provide an excel table in the case of major reprogramming.

No reprogramming is required.

- requires use of the unallocated margin under the relevant heading of the MFF and/or use of the special instruments as defined in the MFF Regulation.

Explain what is required, specifying the headings and budget lines concerned, the corresponding amounts, and the instruments proposed to be used.

- requires a revision of the MFF.

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.

### 3.2.5. *Third-party contributions*

The proposal/initiative:

- does not provide for co-financing by third parties
- provides for the co-financing by third parties estimated below:

Appropriations in EUR million (to three decimal places)

	Year N <sup>63</sup>	Year N+1	Year N+2	Year N+3	Enter as many years as necessary to show the duration of the impact (see point 1.6)			Total
Specify the co-financing body								
TOTAL appropriations co-financed								

<sup>63</sup> Year N is the year in which implementation of the proposal/initiative starts. Please replace "N" by the expected first year of implementation (for instance: 2021). The same for the following years.

**3.3. Estimated impact on revenue**

- The proposal/initiative has no financial impact on revenue.
- The proposal/initiative has the following financial impact:

- on own resources
- on other revenue

please indicate, if the revenue is assigned to expenditure lines

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative <sup>64</sup>							
		Year N	Year N+1	Year N+2	Year N+3	Enter as many years as necessary to show the duration of the impact (see point 1.6)			
Article .....									

For assigned revenue, specify the budget expenditure line(s) affected.

/

Other remarks (e.g. method/formula used for calculating the impact on revenue or any other information).

/

<sup>64</sup> As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 20 % for collection costs.